**Guidance On The Content Of Premarket Notification [510(K)] Submissions For Protective Restraints (Text Only)**

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**GUIDANCE ON THE CONTENT OF PREMARKET NOTIFICATION [510(K)] SUBMISSIONS FOR PROTECTIVE RESTRAINTS**

 GUIDANCE

 ON THE CONTENT OF

 PREMARKET NOTIFICATION [510(K)] SUBMISSIONS

 FOR PROTECTIVE RESTRAINTS

 GENERAL HOSPITAL DEVICES BRANCH

 DIVISION OF DENTAL, INFECTION CONTROL AND GENERAL HOSPITAL DEVICES

 OFFICE OF DEVICE EVALUATION

 DECEMBER 1995

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I. INTRODUCTORY INFORMATION

A. Background and Scope

 Protective restraints, as defined in Section I.C., Page 2,

 have been implicated in numerous injuries and deaths from

 asphyxiation. Vests and jackets have been involved most

 frequently, although body holders also have been reported on

 occasion. Human factors issues such as inadequate warning

 labels, difficult-to-read user instructions, and design

 deficiencies may contribute to accidents.

 In order to help address the problems, on [DATE] FDA revised

 the protective restraint and wheelchair accessory

 classification regulations to require premarket notification

 510(k) submissions for protective restraints not already

 regulated under another classification [FR REFERENCE].

 Under the revised rules, a 510(k) is required (1) for any

 protective restraint intended to be introduced into

 commercial distribution on or after [DATE], and (2) for any

 protective restraint already in commercial distribution or

 that is marketed prior to [DATE].

 This document provides guidance on the form and content of

 510(k)s for protective restraints. The document is also a

 voluntary guide for persons marketing devices which may have

 protective restraints as components, such as operating

 tables and chairs that are regulated under other devices

 that are exempt from 510(k) requirements. Devices

 pertaining to this guidance include wristlets, anklets,

 vests, straight jackets, body/limb holders, and other types

 of protective restraints that are intended for medical

 purposes.

 Other relevant guidance documents that contain additional

 information are referenced in Section I.F., Supplementary

 Guidance, on Page 4.

B. Purpose

 As noted, manufacturers of protective restraints, including

 those devices already in commercial distribution and

 previously exempted from premarket notification, are

 required to submit a premarket notification to FDA.

 Therefore, this guidance is intended:

 1. to guide FDA review staff in conducting and documenting

 the review of premarket notifications for protective

 restraint devices;

 2. to assist persons (i.e., manufacturers, distributors,

 or importers) in assembling and organizing premarket

 notifications for protective restraints; and

 3. to achieve consistency in content of the 510(k)s in

 order to facilitate document review.

C. Definitions

 1. Accessory Device: a device that aids or contributes in

 a secondary manner to the effectiveness of another

 device (e.g., wheelchair accessories ref. 21 CFR

 890.3910).

 2. Intended Use: the objective intent of the persons

 legally responsible for the labeling of the device.

 The intent is determined by such persons' expressions

 or may be shown by the circumstances surrounding the

 distribution of the device. The objective intent may,

 for example, be shown by labeling claims, advertising

 matter, oral or written statements by such persons or

 their representatives. It may be shown by the

 circumstances that the device is, with the knowledge of

 such persons or their representatives, offered and used

 for a purpose for which it is neither labeled nor

 advertised (ref. 21 CFR 801.4, FDA Labeling).

 3. Labeling: all labels and other written, printed, or

 graphic matter (1) on any device or any of its

 containers or wrappers, or (2) accompanying such device

 (ref. Sec. 201, F,D,& C Act)

 4. Protective Restraint: a device, including but not

 limited to, a wristlet, anklet, vest, mitt, straight

 jacket, body/limb holder, or other type of strap that

 is intended for medical purposes and that limits the

 patient's movements to the extent necessary for

 treatment, examination, or protection of the patient or

 others

 (ref. 21 CFR 880.6760).

 5. Vehicle: for purposes of this guidance, the object to

 which a restraint is attached (e.g., a bed, wheelchair

 or stretcher).

D. Abbreviations

 AAMI Association for the Advancement of Medical

 Instrumentation

 ANSI American National Standards Institute

 ASTM American Society for Testing and Materials

 CDRH Center for Devices and Radiological Health

 CFR Code of Federal Regulations

 DSMA Division of Small Manufacturers' Assistance

 FDA Food and Drug Administration

 FR Federal Register

 HCFA Health Care Financing Administration

 ISO International Organization for Standardization

 MDR Medical Device Report

 NSE Not Substantially Equivalent

 OBRA Omnibus Budget Reconciliation Act

 ODE Office of Device Evaluation

 PMA Premarket Approval Application

 PRP Product Reporting Program

 SMDA Safe Medical Devices Act of 1990

E. General Principles Regarding Presentation of Data

 1. Editorial Considerations: The 510(k) should be

 carefully edited, as well as scientifically reviewed,

 before it is submitted to FDA. It should be proofread

 to assure that all pages/sections are included and are

 properly indicated, consecutive, distinctly copied and

 legible.

 2. Abbreviations: Standard abbreviations acceptable to a

 significant peer reviewed journal should be used

 wherever possible. All other abbreviations should be

 identified at the beginning of each section in which

 they are used or in footnotes to tables and graphs.

 3. Data Availability: This document outlines typical

 circumstances of data review. It is not possible to

 anticipate all situations that may require FDA review.

 Thus, those submitting applications should be aware

 that they may be asked to submit additional data, to

 present data in another format or to provide more

 detailed explanations of the information submitted if

 required to establish equivalence.

 Applicants should keep data used for the 510(k)

 submission on file in a controlled and well-organized

 format. This will allow the applicant to expeditiously

 supply FDA with additional information or analysis, if

 required. Errors in data that are identified by the

 applicant after submission to FDA should be brought

 immediately to FDA's attention.

 4. Tables and Graphs: Well-constructed tables are

 fundamental to the reporting and evaluation of data.

 All tables should be clearly identified and captioned

 with symbols keyed to a footnote or accessible

 reference page that adequately indicates the nature of

 the data.

 Graphs should supplement, not replace, data tables.

 They should be of a high quality.

 5. Published Literature: Published methods or data

 referenced in study reports should be made available to

 FDA upon request. Reprints of other referenced

 published or unpublished reports or data should also be

 made available to FDA upon request. All referenced

 reports and data should be summarized including an

 explanation regarding how it relates to the current

 submission. Reference citations should be complete

 (e.g., title, author, volume and year).

 6. Protocols and Data Analysis: Test reports must include

 the protocol (objectives, precise description of

 materials, experimental methods and controls),

 observations, statistical methods and analyses,

 conclusions and comments. Do not submit raw data

 unless requested to do so by FDA. Additional specific

 directions on protocols are included in sections that

 follow.

 7. Reference to Submitted Data: In support of the 510(k),

 the applicant may reference any information previously

 submitted to FDA. If the applicant did not submit the

 referenced data, he must provide a letter of

 authorization. Often, if the data are not extensive,

 resubmitting data in the 510(k) will facilitate the

 review of the document.

F. Supplementary Guidance

 The following relevant guidance documents are available from

 DSMA [(800)638-2041 or (301)443-6597], unless otherwise

 indicated:

 1. Biological evaluation of medical devices - Part 1:

 Evaluation and Testing ISO 10993.

 2. ODE Blue Book Memorandum #K86-3, Premarket Notification

 Review Program.

 3. Write It Right: Recommendations for Developing User

 Instruction Manuals for Medical Devices Used in Home

 Health Care (HHS Publication FDA 93-4258).

 4. Human Factors Principles for Medical Device Labeling.

 5. ANSI/AAMI HE48-1993: Human factors engineering

 guidelines and preferred practices for the design of

 medical devices (available from the Association for the

 Advancement of Medical Instrumentation: (703) 525-4890,

 or (800) 332-2264).

 6. "Medical Devices: protective restraints; revocation of

 exemptions from 510(k) premarket notification

 procedures and current good manufacturing practice

 regulations," Proposed Rule, June 19, 1992 (57 FR:

 27397-27400).

 7. ANSI Z535, Committee on safety signs and colors, New

 York, 1991.

 8. ODE Blue Book Memorandum #G91-1, Device Labeling

 Guidance.

 9. Omnibus Budget Reconciliation Act of 1989 (OBRA '87).

 10. 21 CFR Part 801, Device Labeling

 11. Proposed and Final Rules (Federal Register) pertaining

 to 21 CFR Part 880, General Hospital and Personal Use

 Devices and Part 890, Physical Medicine Devices.

 12. Labeling Regulatory Requirements for Medical Devices

 (FDA 89-4203).

 DSMA also has additional guidance documents that are

 generally relevant to the marketing of medical devices, such

 as guidance on good manufacturing practices.

G. The FDA Review Process

 Questions often arise regarding the FDA review process for

 510(k) submissions. The following is a brief outline of

 that process.

 Administrative Review

 1. The applicant submits a 510(k) to the FDA Document Mail

 Center.

 2. The Document Mail Center assigns the 510(k) number and

 determines if the 510(k) states the classification for

 the device.

 If it does not include the FDA device class, then

 the applicant is notified by phone that they

 should amend the 510(k) to note the class, and the

 submission is placed on hold.

 If it includes the class, then an acknowledgement

 of receipt letter is sent to the applicant.

 3. The 510(k) with the class information is directed to

 the reviewing division.

 4. Division personnel conduct an initial administrative

 review of the 510(k) to determine if it includes the

 basic information required by regulation. The document

 is also administratively triaged into one of three

 levels or Tiers which determines the type of scientific

 review that will be afforded the device. Tier 1

 devices have a limited review while Tier 3 devices have

 a comprehensive and rigorous review. Protective

 restraint devices are considered Tier 2 devices at this

 time requiring focussed scientific review.

 If the 510(k) is not administratively complete,

 then the submission is placed on hold by a letter

 that is sent to the applicant explaining the

 administrative deficiencies.

 If it is complete, then the submission is placed

 in a queue for the scientific review, appropriate

 for the assigned Tier.

Scientific Review

 Substantial equivalence is determined as detailed in the

 Blue Book 510(k) Memorandum #86-3 available from DSMA.

 Basically, there are four main questions the FDA reviewer

 considers:

 1. Does the new device have the same intended use as the

 legally marketed device that is identified by the

 applicant?

 2. Does the new device have the same technological

 characteristics (i.e., design, materials, energy

 source, etc.) as the legally marketed device?

 3. Does evaluation of the new device and its technology

 raise new types of safety or effectiveness questions

 when compared to the legally marketed device?

 4. Are performance data needed to determine if the new

 device is as safe and effective as the legally marketed

 device?

 There are basically one of three outcomes from the

 scientific review:

 1. The device is determined to be substantially equivalent

 to a legally marketed device and for which premarket

 approval is not required, and a letter is sent to the

 applicant which allows the device to be legally

 marketed.

 2. The reviewer needs more information to complete the

 review. The reviewer either calls the applicant or FDA

 sends a letter, depending on the complexity of the

 deficiencies or questions. If the reviewer calls, the

 510(k) may be placed on an administrative hold status.

 If FDA sends a letter then either: (1) a 30 day limit

 is placed on the response time, or (2) FDA considers

 the 510(k) withdrawn due to the complexity of the

 deficiencies.

 If more information is requested, and the submission is

 not considered withdrawn, the review stops until the

 information is received. When the applicant submits a

 response the reviewer places the amended 510(k) in a

 separate amendment queue for review.

 If the information is not received in the time

 frame noted in the deficiency letter, or as

 requested over the telephone, then the submission

 is considered withdrawn.

 If received, but not complete, FDA may find the

 device not substantially equivalent or may ask for

 more information, and another supplement is

 required.

 3. The device is found not substantially equivalent (NSE).

 An NSE device requires an approved PMA or it must be

 reclassified into Class I or II before it may be

 legally marketed.

H. Standards

 The applicant may list relevant standards and certify that

 the device meets the standards (e.g., AAMI, ASTM, ISO,

 etc.). The applicant then is obliged to meet the standard

 and maintain documentation of testing showing that the

 device meets the standard. Certification of meeting a

 specific standard and reference to standards in the 510(k)

 may reduce the documentation needed in the 510(k)

 submission, as noted in the sections on specifications and

 testing.

II. CONTENT AND ORGANIZATION OF 510(K)S FOR PROTECTIVE RESTRAINT

 DEVICES

A. Cover Letter

 The 510(k) should begin with a cover letter that clearly

 identifies the submission as a 510(k). Title 21 CFR 807.87

 specifies information that is required in the 510(k). The

 information required under 807.87(a),(b),(c), and (d) can

 be included in the cover letter. Table 1 notes the required

 class, panel number, product code and the common names that

 are used for protective restraints (ref. FDA Publication 91-4246,

 Classification Names for Medical Devices and In Vitro

 Diagnostic Products).

 **Table 1**

|  |
| --- |
|  |

|  |  |  |  |
| --- | --- | --- | --- |
| Class | Panel | Procode | Common Name |
| I | 80 | PMQ | ProtectiveRestraint |
| I | 89 | KID | WheelchairAccessory |

B. Labeling

 1. General Information for the Applicant

 a. The submission must contain proposed draft or

 final labeling (ref. 807.87(e)). Labeling

 includes LABELS affixed to the device, container,

 and/or packaging. Labeling also includes

 professional and patient package INSERTS, POSTERS

 and any other information accompanying the device

 (e.g, video training).

 b. Labeling is the primary emphasis of this guidance.

 Special attention is given to information related

 to human factors issues such as restraint

 application and fastening, positioning and

 orientation, size selection, and patient

 monitoring.

 c. Some of the guidance related to human factors

 issues are not uniformly applicable to all

 restraint types. Applicants should tailor the

 labeling to the specific protective restraint.

 Consider both the design and the hazards

 associated with the specific use of the device.

 d. The labeling must comply with 21 CFR 801, the

 general labeling regulations. This guidance

 provides additional labeling recommendations. The

 recommendations provide latitude because of

 differences in device design, size, and available

 labeling space.

 The applicant should also include a summary

 analysis of the literature, if any, relevant to

 the specific design of the restraint submitted for

 review.

 e. FDA recommends that applicants consider label

 positions and configuration carefully, that is,

 where labels are placedand how they are arranged.

 For example, a warning attached to the outside of

 a restraint should advise a user not to tie the

 restraint to an inappropriate part of the bed. It

 is recommended that labels be oriented so that

 they can be read without turning the device

 upside-down. In addition to providing written

 information, a prominent label on the outside of

 the device also may serve as a marker immediately

 alerting the staff to improper positioning on the

 patient (e.g., label appears at bottom, instead of

 top, after upside-down placement).

 f. Labels and labeling should be legible and designed

 for readability and comprehension (see Write It

 Right). Thus, type size, wording, readability,

 graphics, step-by-step procedures, highlighting,

 blank space, legibility, use of color, formatting,

 reading level, sentence length, writing style,

 etc. are all important. For example, large type

 sizes are best for reading under poor lighting

 conditions by a wide range of device users. Also,

 user reading levels should be considered with

 respect to vocabulary and sentence structure.

 g. Applicants should consider providing instructions

 in both English and other common languages.

 h. Recommended formats for pictorials and a sizing

 guide for use in labeling are included in the

 Appendix.

 2. Labeling Requirements and Recommendations

 a. Package Labels

 Labeling on the packaging should include the

 following information:

 name of product, type of restraint,

 manufacturer or distributor (with address),

 number of components, and net quantity;

 size; and

 a prescription labeling statement which reads

 as follows: "Caution: Federal law restricts

 this device to sale by or on the order of a

 physician or licensed healthcare

 practitioner."

 b. Device Labels

 The protective restraint itself should display the

 following information:

 the manufacturer and product identification;

 on vests, jackets and other upper torso

 restraints (e.g., bodyholders) a position

 label noting the orientation of the device on

 the patient (e.g., top/bottom, front/back,

 inside/outside).

 NOTE: The applicant may consider combining

 different position markers into a single

 label on one side of the vest (e.g.,

 "outside/top/back").

 the common size (e.g., small, medium, large)

 plus body measurements and weight ranges (see

 Appendix);

 a cleaning instruction label, if appropriate;

 specific warnings related to incorrect

 placement, wrong size, improper application

 to the "vehicle", knots preventing quick

 release and the use of restraints in

 damaged/poor condition;

 pictorials illustrating hazards (e.g.,

 proper/improper placement) to the patient,

 when appropriate (see Appendix);

 cautionary information about the need for

 frequent patient monitoring and device

 flammability; and

 the most important application steps,

 whenever possible.

 c. Instructions For Use

 The instructions for use (e.g., package

 insert, poster, etc.) should include the

 following: manufacturer's name and address;

 description of restraint; sizing table;

 indications for use; contraindications;

 warnings and precautions; application and

 fitting instructions; and the FDA required

 prescription statement from Section 801.

 NOTE: Ample use of pictorials is highly

 recommended.

 Labeling should advise restraint users to

 consult their hospital policy or the

 individual(s) prescribing the use of the

 device for further directions on (1) wearing

 time/release intervals, and (2) frequency of,

 and reasons for, patient monitoring and

 supervisory requirements. Labeling should

 also recommend periodic refresher training.

 Each piece of labeling should pertain to only

 a specific model unless all the instructions

 in the piece of labeling applies to all the

 models listed.

C. Device Description

 The applicant must include in the 510(k) a complete

 description of the protective restraint, including ALL

 variations of the device. The description should include:

 1. General Description

 Provide a detailed description of the protective

 restraint design including any straps, buckles, other

 attachments or accessories.

 2. Drawing/Picture

 Provide clear pictorial and labeled representation of

 the device. Poor quality pictures will delay

 processing of the 510(k). The labeling may have

 sufficient representations (e.g., graphic

 illustrations) for review purposes. If this is the

 case, then the applicant should refer FDA to the

 labeling.

 3. Intended Use

 Provide clear statements of all intended uses for the

 subject protective restraint. The intended use should

 address the intended patient condition(s), (e.g.,

 postural support, severe agitation, etc.) and

 vehicle(s) to which the protective restraint may be

 attached (e.g., wheelchair or bed). Provide clear

 statements of all claims pertaining to the subject

 protective restraint. The intended use and claims must

 be consistent with the labeling.

 The intended use statements and claims must be

 supported by comparison to a legally marketed

 protective restraint. The scope of use and claims are

 very important in defining the type and amount of data

 that is needed in the 510(k) submission, and defined in

 Section E of this document.

 4. Specifications

 The applicant should provide the applicable

 specifications noted below. State the specification

 and tolerances, and provide a summary of all supporting

 test data which validate that the device meets the

 stated specifications.

 The applicant may refer to an accepted, relevant

 industry standard and certify that they will meet the

 standard as supporting evidence. Section II.E.,

 Performance Data, provides further directions on test

 data.

 The applicant should provide the rationale for each

 specification. For example, the applicant should cite

 data relevant to size specifications. If possible,

 applicable anthropometric data, standards, research and

 guidelines should be referenced. Comparison of

 specifications to other legally marketed protective

 restraints may also suffice.

 a. Physical Specifications

 (1) Sizing: Provide a chart of the specified

 sizes and dimensions (see Appendix). The

 sizing should be based upon available

 anthropometric data reflecting dimensions

 (weight, extremity circumference, chest size,

 trunk length, etc.) for typical patient

 populations. Address, the following factors

 in the rationale for the sizing

 specifications:

 Male/Female

 Adult/Pediatric

 Older Adult compensations

 (2) Color (e.g., size coding, see Appendix):

 Different colors should be used to

 differentiate sizes. There is no standard

 color coding, however, FDA strongly

 recommends that the color codes in the

 Appendix be used. FDA will acknowledge a

 request in the 510(k) to allow for a

 transition to the recommended color code in

 order to permit depletion of current stock

 and to make manufacturing changes, as needed.

 The transition period should not exceed 180

 days. State the original color scheme for

 the record. FDA will consider alternatives

 but the applicant should provide ample

 justification.

 (3) Special features: Any other unique physical

 features and specifications of the protective

 restraint should be noted.

 (4) Overall: Describe keyed locks or design locks

 and any pressure relief accessories

 (e.g., gel foam, lambs wool).

 b. Mechanical Specifications

 (1) Include all mechanical specifications in the

 premarket notification including those of the

 following components:

 buckles

 belts

 hooks

 snaps

 straps

 ties

 locks and accessories

 (2) Mechanical specifications should include, but

 not be limited to the following:

 Basis for the criteria

 Strength of connection mechanism to device

 including failure strength of components

 Tensile strength of materials including

 pass/fail criteria

 Reuse durability of device and attached

 labels

 5. Materials

 Provide a complete listing of all materials used in the

 construction of the protective restraint. This should

 include the materials used for all attachments such as

 buckles, ties, etc. Identify all colors (e.g., ink,

 dyes) used in manufacturing the device. Flame

 retardant materials should be described if utilized.

 6. Biocompatibility

 The materials, including colors, should meet

 biocompatibility requirements in accordance with the

 ISO 10993.

D. Descriptive Comparison to a Legally Marketed Device

 According to 21 CFR 807.87(f), a premarket notification

 must include a comparison of the new device to a legally

 marketed device. The purpose of this comparison is to help

 FDA establish that the new device is as safe and effective

 as the claimed legally marketed device. Therefore, FDA has

 called for 510(k)s for ALL protective restraints, new ones

 as well as those previously marketed due to safety concerns.

 1. If a protective restraint was on the market prior to

 May 28, 1976 (preamendment) and has not since that date

 been modified in a manner that would significantly

 affect the safety or effectiveness of the device or

 undergone a major change or modification in the intended use of the

 device, a 510(k) is not required. See 21 CFR 807.81.

 2. All other protective restraints modified as described

 above or marketed on or after May 28, 1976 must be the

 subject of a 510(k) to be legally marketed.

 The applicant should include the following comparisons

 of the new device and a legally marketed device (i.e. a

 preamendment device or device that has been found

 substantially equivalent to a legally marketed device

 by FDA) in the 510(k) submission:

 a. Compare and contrast the intended use and all

 claims of the new device to the claimed legally

 marketed predicate device(s). Compare and

 contrast other aspects of labeling (labels,

 instructions for use, promotional material). To

 facilitate comparison, also include clear

 representations of the legally marketed device(s).

 b. Compare and contrast all materials used to

 fabricate the device.

 c. Compare and contrast the technological aspects.

 d. Compare and contrast the specifications, test, and

 performance data.

E. Performance Data

 1. Introduction

 Performance data should be submitted for protective

 restraints. The applicant must establish with test

 data that the new restraint is as safe and effective as

 a legally marketed restraint for the same intended use.

 The applicant should provide the test protocol, all

 data or summary data and a full presentation of the

 results. The test protocol should include the

 objective, sampling plan, response variables, pass/fail

 criteria, basis for criteria, a summary of the data,

 analysis (statistical when possible), and conclusions.

 This guidance does not prescribe any specific test

 protocols. Rather, the guidance provides overview

 information and several considerations that FDA

 believes will assist applicants. There are standard

 methods that may be used for engineering bench tests.

 If used, the standard should be referenced. If there

 is no standard method for a test, then the applicant

 should devise a scientifically sound test method that

 meets the stated test objective.

 2. Types of Performance Tests

 The applicant should submit at a minimum bench,

 biocompatibility, and simulated use test data. In the

 case of significant new designs, FDA may require

 prospective clinical trials, as well. In lieu of test

 data, FDA will consider scientifically sound

 alternative information which addresses concerns

 related to the performance and biocompatibility of the

 restraint. Prospective clinical or animal data will be

 requested on a case-by-case basis.

 a. Bench Tests

 Device specifications and related labeling

 statements should be validated by bench and other

 engineering tests. For instance, the specified

 strength of a belt or material should be verified

 and the basis for the strength specification must

 be explained.

 b. Biocompatibility Tests

 In order to validate material biocompatibility,

 the applicant should either (1) certify that the

 identical materials for each component, including

 fabrics, dyes or colors, have been used in other

 legally marketed devices with the same or similar

 intended use or (2) provide test results in

 accordance with the ISO 10993.

 c. Simulated Use Tests

 As explained in Section II.E.4., the 510(k) should

 include data from tests using health care

 workers who typically use the type of device

 (nurses, aides, technicians, etc). The following

 sections provide more detail on the applicable

 tests including important factors to consider.

 3. Performance Data Considerations

 a. The applicant should submit ALL valid scientific

 evidence (either prospective or retrospective)

 which they believe may help demonstrate that their

 protective restraint is safe and effective.

 b. Performance data should support the claims and

 intended use for the device.

 c. FDA will consider arguments for foregoing

 simulated use tests for new restraints with

 identical design and labeling to a legally

 marketed restraint.

 d. There are several types of protective restraint

 devices, and studies must be adapted to the

 variables associated with the particular devices.

 For instance, vests and jackets represent different use and

 safety factors than do wrist restraints. Thus

 studies of the latter will include some factors

 not represented in the study of vests and jackets

 and vice versa.

 e. The applicant must consider the nature of the

 population of patients and users associated with a

 device study. The prevalence and incidence of

 protective restraint injuries may vary between

 institutions, within different services in the

 same institutions, and within services over time.

 Training, experience, native language, and the

 learning curve of users will also vary.

 Therefore, the people selected to test the devices

 should be representative of the population of

 users.

 4. Elements of a Simulated Use Study

 a. Introduction

 To validate device labeling and design, the

 applicant should conduct simulated use tests. The

 simulation should mimic clinical use with respect

 to the user and subject population, the

 fitting/attachment procedures used, the labeling,

 and the conditions of use.

 The "users" are the individuals fitting and

 applying the devices, while the "subjects" are the

 individuals to whom the restraints will be fitted

 and attached.

 Data based on the use of instructional models is

 not sufficient to establish substantial

 equivalence. If not conducted under actual

 institutional conditions, the protocol should

 replicate to the extent possible as many

 conditions as is feasible (e.g., lighting, real-world

 requirements for speed of attachment, etc.).

 The data should demonstrate that the device

 function will be reliable and reproducible as

 intended under controlled conditions when used as

 indicated in labeling.

 The simulated, controlled use tests should be

 designed to (1) isolate problems with the device

 and optimize the design, (2) identify deficiencies

 in labeling, and (3) evaluate the type of training

 needed.

 There are no standardized, validated methods to

 simulate clinical use of protective restraints,

 and thus the applicant must devise a

 scientifically valid protocol. The protocol

 should be comprehensive (e.g., must include the

 objective, manner of subject selection,

 independent variables, measures, etc.). Some

 considerations for the test are discussed below.

 b. Study Considerations

 The users should be actual nurses, nurses aides,

 and lay care givers.

 Volunteer subjects may be individuals selected

 from either institutional or non-institutional

 settings (company subject pools, etc.).

 Bias should be minimized by the selection of a

 justified sample size of participants to provide

 balanced subjective and objective performance

 measures.

 The test evaluators and subjects should have no

 conflicting interest in the device, although they

 may be compensated for their participation.

 Test protocols should yield both subjective data

 (e.g., labeling preferences; opinions about device

 fitting and attachment; etc.) and behavioral data

 (time to read instructions and attach/release

 device; snugness of attachments; neck clearance

 and overall fit; errors; false starts; etc.).

 The behavioral and study variables should include

 the following: selection of restraint by size

 (e.g., from bin or shelf in which collectively

 stored); vehicle to which attached (e.g., bed,

 wheelchair, gerichair, etc.); experience level of

 user; behavior of "subject" (e.g., slumping over,

 etc.); label design (format, font size, wording,

 etc.); label configuration and positioning; and

 lighting conditions during restraint attachment.

 Should the applicant be testing a new design, it

 should be tested against a legally marketed device

 having the same intended use, whenever possible.

 c. Test Preparation and Report

 Commencement of the study should be preceded by a

 program to instruct the participants on the study

 protocol to ensure

 (1) uniformity of test procedures, (2) consistent

 observations, scoring, and evaluations, and (3)

 complete data collection.

 The evaluators should enter the test results on

 report forms. Separate forms may be used to

 report adverse effects and performance.

 d. Report Forms

 The report form should include various types of

 queries, quantitative data, observations, and

 narrative comments. The applicant should consider

 the following data elements (not necessarily an

 exhaustive list):

 (1) general tracking information, such as date,

 time periods, name of institution,

 evaluator's name, etc;

 (2) numbers and types of tested devices;

 (3) graded ability to attach/fit the devices,

 select correct size, read and understand the

 labeling, etc;

 (4) discrete errors and safety impacts;

 (5) observational descriptions (e.g.,

 unanticipated behaviors, ease of

 attachment/release, etc.);

 (6) labeling preferences, problems, design flaws,

 and recommended changes;

 (7) additional training requirements; and

 (8) impact of the time to install the device upon

 user acceptance.

 5. Summary

 The critical points of the performance section are as

 follows:

 Performance data should always include bench,

 biocompatibility, and simulated use data or

 scientifically valid alternatives which address

 concerns related to the labeling, device

 performance and the biocompatibility of the

 protective restraint.

 All important response variables should be

 considered when devising the study.

 Simulated tests usually will be sufficient in

 cases in which the device design does not differ

 significantly from existing devices. In selected

 cases, FDA may require prospective clinical

 testing.

 6. Additional Data Requirements

 FDA cannot anticipate all situations that may exist for

 a particular restraint design in a 510(k). Therefore,

 FDA maintains its prerogative to request additional

 information not specified in this guidance.

F. Features of Safe and Effective Protective Restraint Devices

 Effective, safe protective restraint use will not be

 achieved as a result of this guidance alone. Many other

 actions will help, such as adequate education and training

 of personnel. With respect to restraint characteristics,

 the following features are especially desirable:

 Position (e.g., "top") and size are clearly marked on

 the device.

 Pictorial and written warnings about misapplication,

 incorrect sizes, and the hazards of attaching to the

 wrong fixture are labeled so that they are obvious to

 the person attending the patient.

 The device should be designed such that it is

 reasonably easy to apply and does not in any way

 present a danger to the patient.

G. Future Revisions

 This guidance will be amended based on public and potential

 FDA advisory committee comment. Until, and unless, it is

 amended, this document serves as the FDA current

 recommendations for a 510k. More specifics may be provided

 in future revisions.

Appendix 1

 **Example of Comparison Table**

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| --- |
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|  |  |  |
| --- | --- | --- |
| FACTORS | NEW DEVICE | LEGALLY MARKETED DEVICE |
| intended useand claims |   |   |
| technologicalfeatures |   |   |
| materials |   |   |
| specifications:physicalmechanical  |   |   |
| other |   |   |

[Appendices 2, 3, 4 and 5 can be viewed in pdf format.](https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080294.pdf)

https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080287.htm