**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 | Protective Restraint |
| I | 89 | KID | Wheelchair Accessory |

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**

|  |
| --- |
|  |

|  |  |  |
| --- | --- | --- |
| FACTORS | NEW DEVICE | LEGALLY MARKETED DEVICE |
| intended use and claims |  |  |
| technological features |  |  |
| materials |  |  |
| specifications:  physical  mechanical |  |  |
| 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