Premarket Approval Applications (PMA) for Sharps Needle Destruction Devices; Final Guidance for Industry and FDA

Document issued on: March 2, 2001

This document supersedes Draft Guidance on the Content and Format of Premarket Approval Applications (PMA) for Sharps Needle Destruction Devices - 2/11/97

U.S. Department Of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Infection Control Devices Branch
Division of Dental, Infection Control and General Hospital Devices
Office of Device Evaluation

Preface

Public Comment

Comments and suggestions may be submitted at any time for Agency consideration to Dockets Management Branch, Division of Management Systems and Policy, Office of Human Resources and Management Services, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852. When submitting comments, please refer to the exact title of this guidance document. Comments may not be acted upon by the Agency until the document is next revised or updated.

For questions regarding the use or interpretation of this guidance contact Dr. Chiu S. Lin at 240-276-3700 or by email chui.lin@fda.hhs.gov.

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TABLE OF CONTENTS

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This document is intended to provide guidance. It represents the Agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind the Food and Drug Administration (FDA) or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

I. INTRODUCTION

A. Scope

The purpose of this document is to provide guidance to manufacturers on the type of issues and areas of concern that need to be addressed in a premarket approval (PMA) application for sharps needle destruction devices to be used in health care facilities. For complete details on the PMA process, manufacturers should review the Premarket Approval Manual (PMA Manual) before using this document.

This guidance document primarily focuses on devices that are used in health care facilities to incinerate needles still attached to a syringe. However, many issues described in this document may also apply to devices that use other methods of needle destruction or to needle destruction devices intended for home use only. FDA encourages the sponsor of any type of needle destruction device to contact the Infection Control Devices Branch to arrange a presubmission meeting with FDA representatives. At this meeting, we will discuss protocols and data needed for the specific device before the submission of a PMA.

THE LEAST BURDENSOME APPROACH

The issues identified in this guidance document represent those that we believe need to be addressed before your device can be approved/cleared for marketing. In developing the guidance, we carefully considered the relevant statutory criteria for Agency decision-making. We also considered the burden that may be incurred in your attempt to comply with the guidance and address the issues we have identified. We believe that we have considered the least burdensome approach to resolving the issues presented in the guidance document. If, however, you believe that information is being requested that is not relevant to the regulatory decision for your pending

application or that there is a less burdensome way to address the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center webpage at: http://www.fda.gov/cdrh/modact/leastburdensome.html

B. Background

This guidance was developed by the Infection Control Devices Branch, Division of Dental, Infection Control and General Hospital Devices (DDIGD), Office of Device Evaluation (ODE), Center for Devices and Radiological Health (CDRH), Food and Drug Administration (FDA).

FDA placed sharps needle destruction devices in Class III because the technological characteristics of the sharps needle destruction devices raise new types of safety and effectiveness questions when compared to conventional sharps disposal containers. To date, FDA has approved several needle destruction devices that incinerate the sharp. One of the devices leaves a blunted hub and does not require that the syringe be deposited in a conventional sharps container.

This guidance document describes the type of information needed for a manufacturer to demonstrate the safe and effective use of their sharps needle destruction device. When we developed this guidance document to aid manufacturers in submitting a PMA, we considered a variety of factors, including:

- Our PMA review experience with sharps incineration devices
- Our recognition that each additional step (manipulation) in the needle disposal process has the potential for increasing the risk to the user
- The Occupational Safety and Health Administration (OSHA) Regulations on Bloodborne Pathogens (29 CFR Part 1910.1030)
- The Center for Disease Control and Prevention (CDC) recommendations in "Recommendations for Prevention of HIV Transmission in Health-Care Settings," (Morbidity and Mortality Weekly Report, supplement, August 21, 1987)

FDA regulates the introduction of medical devices into interstate commerce. A person intending to market a sharps needle destruction device must submit a premarket approval (PMA) application to FDA prior to its introduction into interstate commerce. Regulations governing the general content and format of PMA submissions are codified under 21 Code of Federal Regulations, Part 814. These and other regulatory requirements pertaining to the marketing of a new medical device are discussed in the PMA manual available from the CDRH Division of Small Manufacturers Assistance (DSMA). The intent of this guidance document is to provide PMA applicants with specific directions regarding information and data that should be submitted to FDA in a PMA submission for a sharps needle destruction device. This guidance should be followed whenever possible. An explanation of any omissions should be provided. **This document is a supplement to the PMA Manual. Please carefully review the PMA Manual before using this guidance document**

for sharps needle destruction devices.

Comprehensive and scientifically sound criteria for the evaluation of sharps needle destruction devices are essential to help ensure that these devices are safe and effective for their intended use when used according to their labeling. FDA recognizes the importance of providing applicants, and other interested parties, with the agency's PMA submission criteria for sharps needle destruction devices. These criteria should facilitate the acquisition of necessary data, maintain consistency of review, and provide for a more efficient regulatory process.

This guidance is predicated upon the legal principles of the PMA process, and expresses FDA's recommendations as of the date noted on the cover page. FDA will periodically revise this document to remain current with developments in this area.

II. GENERAL PRINCIPLES REGARDING PRESENTATION OF DATA

A. Editorial Considerations

Carefully edit and scientifically review the PMA submission before submitting it to FDA. Proofread the document to ensure that all pages are properly indicated, consecutive, distinctly copied, and readable. A well written, well organized, and paginated submission will accelerate the review process.

B. Abbreviations

Use standard abbreviations acceptable to a significant peer reviewed journal wherever possible. Identify all other abbreviations at the beginning of each section in which they are used. Identify all abbreviations that appear in footnotes to tables or in graphs.

C. Data Availability

This guidance document outlines typical circumstances of data review. It is not possible to anticipate all situations that may require further FDA analysis. Thus, be advised that FDA may ask you to submit additional data, present data in another format, or provide a more detailed explanation of the submitted information.

Retain data used for the PMA submission in a well-organized format. This allows you to provide FDA with additional information or analysis expeditiously, if required. Bring errors in data that are identified after submitting the PMA to FDA's attention immediately.

D. Tables and Graphs

Well-constructed tables and graphs are fundamental to the reporting and evaluation of data. Label all tables and graphs with titles that clearly identify the nature of the data. Caption and key all

symbols to a footnote or accessible reference page that clearly explains the nature of the symbols.

Graphs should supplement, not replace, data tables. Tables and graphs should be of a quality acceptable to a significant peer reviewed scientific journal.

E. Published Literature

Append published methods or referenced data to the study report. Append reprints of other referenced published reports or data to the section in which they are referenced. Summarize all referenced reports and data and provide an explanation of how this information relates to the current submission.

F. Protocols and Data Analysis

1. Include the protocol (objectives, precise description of materials, experimental methods, controls), observations, statistical analyses, conclusions and comments for test reports. Other sections of this guidance document address additional specific directions on protocols.

2. Clearly describe analytical methods. These methods should conform to recognized analytical and statistical methods.

III. DATA AND INFORMATION NEEDED IN A PMA

A. Device Characteristics and Manufacturing

1. Physical Description

   a. Provide a complete physical description of the sharps needle destruction device. Include appropriately labeled engineering drawings, which show critical dimensions and tolerances, and photographs showing the device and the location of each component.

   b. Describe the materials used to construct the major device components.

   c. Provide complete specifications for the device, including the physical (all dimensions), mechanical, and electrical (maximum energies used, powers attained) parameters. Provide specifications for the functional characteristics of the device.

   d. Describe the function of each component of the device, including the control and safety mechanisms. Include a discussion of the theory of operation, including normal operation as well as the operation of any safety mechanisms incorporated into the device to minimize risks to the user during fault conditions.

2. Indications for Use/Intended Use

a. Provide a clear, concise intended use statement that includes the specific labeling claims for the use of the device.

b. Identify the intended users of the device, such as healthcare workers or home care patients.

c. Identify the type of facilities in which the device may be used, such as healthcare facilities, a private home, or ambulance.

d. Identify the location for use of the device, such as a patient's room, examination room, emergency room, operating room, dentist's or physician's office, ambulance, laboratory, hospital waste disposal, etc.

e. Identify the specific types and sizes of needles that can be used with the device.

3. Manufacturing

Submit a complete description of the methods, facilities, and controls used in the manufacture, processing, packing, and storage of the device. Include sufficient detail that a person generally familiar with good manufacturing practices can make a knowledgeable judgment about the quality control used in manufacturing the device. For approval, the manufacturing site must pass a Good Manufacturing Practice/Quality Systems Regulation inspection. Please refer to the guidance document, "Guidance for Preparation of PMA Manufacturing Information," which is available from FDA's Division of Small Manufacturer's Assistance (DSMA) at 1-800-538-2041 or at http://www.fda.gov/cdrh/ode/448.pdf for further details.

B. Technical Sections

Unlike most medical devices where the primary safety issues focus on the patient, sharps needle destruction devices also focus on the risks to the users of devices, such as healthcare workers or home care patients. Each additional step (manipulation) in the process to dispose of the needle has the potential for increasing the risk to the user. Thus, information demonstrating the safe and effective use of a sharps needle destruction device should focus on whether or not the additional step of removing the needle from the syringe increases the risk to a user.

Provide data from well-designed, monitored, and controlled studies to demonstrate that the device is reasonably safe and effective for its intended use. The data should meet the regulatory definition of valid scientific evidence as described in 21 CFR 860.7.

Provide data to support each of the performance claims of the subject device. For example, provide performance data to support special design features, such as germicidal ultraviolet lamps or

computer software controlling mechanisms. In each study, include test methodology and/or a protocol, a discussion as to the appropriateness of the selected tests, the study results, a discussion of the study results, and conclusions drawn from the study.

Provide a statistical analysis including the hypothesis to be tested for each study. The number of samples and replicates should be sufficiently large to allow for statistically significant results. State the rationale for the statistical design and methods of data analysis for each study. Refer to the PMA Manual for additional guidance on study design. You may also wish to consult with a statistician.

Provide documentation from a thorough risk analysis, such as a Failure Modes, Effects, and Criticality Analysis (FMECA), which systematically evaluates and documents possible failure modes and the potential impact of each functional or hardware failure on system performance. Discuss the safety of the device. Describe corrective actions which have been implemented to minimize the impact or occurrence probability of each failure mode. Where a functional mechanism has been incorporated into the device design as a preventative measure, provide testing information, including test protocols, results, and conclusions drawn from the results, which demonstrates how a preventative measure will be effective during a fault condition for which it was implemented. Conduct the testing on a statistically evaluable number of samples and adequately stress the performance of each preventative measure.

1. Nonclinical Laboratory Studies

   Information on nonclinical laboratory studies must include a statement that each such study was conducted in compliance with Part 58, Good Laboratory Practice for Nonclinical Laboratory Studies; or, if the study was not conducted in compliance with such regulations, a brief statement of the reasons for the noncompliance.

   Safety Data

   Provide reports, including protocols, for studies conducted to assess the following safety concerns:

   a. The emission of toxic fumes by the device while destroying the needle

   b. The generation of heat by the device while destroying the needle

      In the analysis, evaluate the heat dissipation profile from the heat source to the enclosure surface as well as the point of contact between the held syringe and the user. Include a determination of the maximum temperature seen by the system electronics and a discussion of its effects on circuit performance and component life.

   c. The generation of noise by the device while destroying the needle

d. The formation of sparks while the device is in operation

If the device generates sparks while in use, you should contraindicate it for use in the operation room setting or in other settings with potentially explosive atmospheres, such as where oxygen is in use.

e. The interference with other medical devices

Conduct electromagnetic compatibility testing under conditions that are consistent with the intended environment of device use.

f. The completeness of destruction of the sharps needle

You should note that an incompletely destroyed needle still poses a risk for a sharps injury. If the labeling for a sharps needle destruction device indicates use of the device in place of a sharps disposal container, provide justification for the claim and demonstrate that the remaining nub is no longer a sharp.

g. The stability of the device where it is to be installed, e.g., tabletop or wall mounted during use

h. The formation of an infectious aerosol by the device while destroying the needle

i. The contamination of the surrounding environment with the remaining fluid from the used syringe during the use of the device

j. Other safety issues unique to the device

Effectiveness Data

Conduct the following effectiveness tests with the device to support the product's performance or other special claims, as applicable:

a. Conduct simulated use testing with each type of needle and syringe that is recommended for use with the device. Simulated use tests are controlled tests that allow evaluation of device performance with large numbers and types of soiled or contaminated needles in a controlled environment. These tests should be designed to determine the pass/fail criteria to be used in the clinical study.

b. Since the device is to be reused, conduct studies to validate the device cleaning and decontamination procedures after each use. In addition, provide data to support the use life claimed for the device using soiled and contaminated needles. Refer to

the FDA guidance document entitled, "Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities," April 1, 1996, for further instruction.

c. Validate the software (firmware) if the device includes microprocessor-controlled functions. Refer to the FDA guidance document entitled, "Guidance Document for Computer Controlled Medical Devices," August 29, 1991.

d. If labeling claims that the device removes smoke and odors, conduct testing to support the performance claim.

e. If the device is battery powered, provide data to demonstrate the charge and use life of the battery.

f. If the device is electrically powered, provide the results of electrical testing or demonstrate compliance with a specific standard, such as Underwriters Laboratories and International Electrotechnical Commission IEC 60601.

2. Clinical Investigations

Because sharps needle destruction devices do not make direct contact with patients, sharps needle destruction device testing in health care facilities can be considered a nonsignificant risk study which does not require prior FDA approval under Investigational Device Exemption (IDE) (21CFR 812.2). However, before initiating clinical investigations, the applicant must obtain approval from the Institutional Review Board (IRB) of the site for the proposed study (see 21 CFR 56.103). Provide evidence of IRB approval for each site and confirm the investigator agreements. For further information concerning the IDE regulations and/or IDE requirements, refer to FDA's IDE Manual.

Conduct in-use studies at a minimum of three locations for each health care setting where the device may be used. For example, if the device is indicated for use in a variety of settings within a hospital, then conduct testing in each of the settings, such as operating room, phlebotomy laboratory, or patient room, at three hospitals. If the device is indicated for use in a dental office, then conduct testing in three different dental offices. NOTE: The purpose of in-use testing is to support the product's performance claims, not to determine whether or not the user likes the device. Therefore, design the studies accordingly.

Include the following additional elements in the in-use testing reports:

a. Identify all safety and effectiveness claims for your device and provide the rationale for testing these factors.

b. Describe the endpoints that were measured and the pass/fail and other criteria used to measure the endpoint. Discuss how these endpoints relate to the claims.

c. State the number of investigators/users.

d. Identify the number and types of sites. We recommend using sites that are representative of where the device is indicated for use.

e. Identify the number, types, and sizes of needles and syringes that were tested. We recommend these be representative of the types and sizes of needles and syringes that are compatible with the needle destruction device as defined in the labeling.

f. Include all variables encountered during actual clinical use such as left hand or right hand use, user's height in relationship to the use of the device, gloved or ungloved hand, and other ergonomic concerns.

g. Describe all outcomes and problems, including electrical and operational failures, or other ergonomic outcomes and misuse considerations.

h. Include and describe all appropriate controls in each test.

i. Provide copies of user questionnaires used in the study.

j. State the duration of the clinical in-use study.

k. Conduct a complete statistical analysis of the data.

l. Provide a conclusion for the study.

C. Labeling

1. Device Labels, User Manual, Promotional Material

Submit all medical device labeling, including the device labels, user manual, and promotional material. This material must comply with 21 CFR Part 801. Include the following elements in the labeling:

a. A descriptive statement about the device

b. A statement of the indications for use

c. Contraindication statements which describe situations in which the device should not be used

d. Warning statements that describe potential safety hazards, limitations in use imposed

by them, and steps that should be taken if they occur

e. Statements of precaution that describe any special care that should be exercised by the user

f. Statements of adverse reactions that may occur with use of the device

g. Results of clinical in-use testing

2. Labeling Claims

If you make specific labeling claims, provide data and information that support each specific safety and effectiveness claim. The agency does not allow disease prevention or organism destruction claims, or claims that the device prevents or reduces the incidence of needlestick injury for sharps needle destruction devices unless there is valid scientific evidence to support such claims. However, the sponsor ordinarily may claim that the device destroys the needle and reduces the risk of needlestick injury. In addition, the labeling may claim that the device serves as an alternative to or as an effective substitute for conventional sharps containers for disposal of contaminated sharps needles, if data demonstrate that the remaining needle nub is no longer a sharp.

3. Device Reuse Instructions

In the device labeling/instructions for use, include device reuse instructions that are supported by validation data. Unlike conventional sharps containers, which are disposable and can easily be discarded if they become contaminated, needle destruction devices are very often reusable and require cleaning, decontamination, and maintenance. This additional manipulation could increase the risks faced by the user. Therefore, it is critical that the device be properly reprocessed (cleaned and disinfected) between uses. Refer to the April 1, 1996 guidance document, "Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities" for further instruction.

D. Panel Recommendation

Based on the regulatory discretion provided in section 515(c)(2)(A) of the Food, Drug and Cosmetic Act (the act) as amended by the Safe Medical Devices Act of 1990, this PMA will not be referred to the General Hospital and Personal Uses Devices Panel, an FDA advisory panel, for review and recommendation, unless special circumstances arise.

E. Environmental Assessment

We believe that these devices qualify for an exclusion from an environmental assessment as described under Section 25.22(a)(18). However, you should request an exclusion and provide

justification that establishes to FDA's satisfaction that the requested action is within the excluded category and meets the criteria for the applicable exclusion.

IV. REFERENCES

The following list of ODE Guidance Documents may be helpful in preparing a PMA submission depending on the specific claims made for the device as well as the technological features of the device.

1. Premarket Approval (PMA) Manual, January 1998; HHS Publication FDA 97-4214

2. Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: FDA Reviewer Guide, April 1, 1996

3. Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, May 29, 1998

4. Investigational Device Exemptions (IDE) Manual, June 1996; HHS Publication FDA 96-4159