

P960018



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 16 1998

Mr. Clarke B. Lloyd
Compliance Officer
Healthcare Products Plus, Incorporated
2119 Kenmore Avenue
Chicago, Illinois 60614

Re: P960018
Needlyzer™ - The Needle Destroyer Model ND2
Filed: May 28, 1996
Amended: July 8, 1996; August 26, 1996; October 7, 1996;
January 16, 1997; May 28, 1997; June 13, 1997; August 15,
1997; January 20, 1998; March 5, 1998; March 6, 1998;
May 12, 1998

Dear Mr. Lloyd:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) for the Needlyzer™ - The Needle Destroyer Model ND2. This device is indicated for use as a mobile sharps needle destruction device that is intended to oxidize non-coated stainless steel needles immediately after use. The device will oxidize to the hub butterfly-type needles and all needles 16-30 gauge and 4-52 mm in length attached to a metal or plastic hub or a vacutainer. The device is intended to be used in hospitals and other healthcare facilities. We are pleased to inform you that the PMA is approved subject to the conditions described below and in the "Conditions of Approval" (enclosed). You may begin commercial distribution of the device upon receipt of this letter.

CDRH will notify the public of its decision to approve your PMA by making available a summary of the safety and effectiveness data upon which the approval is based. The information can be found on the FDA CDRH Internet HomePage located at <http://www.fda.gov/cdrh/pmapage.html>. Written requests for this information can also be made to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., Rm. 1-23, Rockville, MD 20857. The written request should include the PMA number or docket number. Within 30 days from the date that this information is placed on the Internet, any interested person may seek review of this decision by requesting an opportunity for administrative review, either through a

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hearing or review by an independent advisory committee, under section 515(g) of the Federal Food, Drug, and Cosmetic Act (the act).

Failure to comply with the conditions of approval invalidates this approval order. Commercial distribution of a device that is not in compliance with these conditions is a violation of the act.

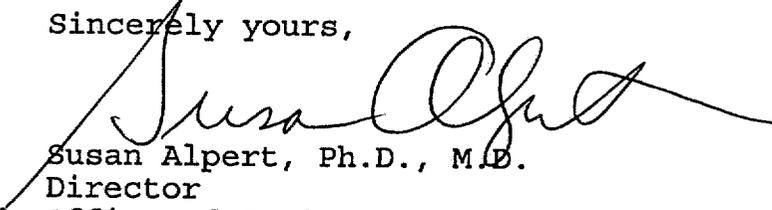
You are reminded that, as soon as possible and before commercial distribution of your device, you must submit an amendment to this PMA submission with copies of all approved labeling in final printed form.

All required documents should be submitted in triplicate, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing.

PMA Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Blvd.
Rockville, Maryland 20850

If you have any questions concerning this approval order, please contact Elaine Schalk Mayhall, Ph.D. at (301) 443-8913.

Sincerely yours,



Susan Alpert, Ph.D., M.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Issued: 3-4-98

CONDITIONS OF APPROVAL

APPROVED LABELING. As soon as possible, and before commercial distribution of your device, submit three copies of an amendment to this PMA submission with copies of all approved labeling in final printed form to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration (FDA), 9200 Corporate Blvd., Rockville, Maryland 20850.

ADVERTISEMENT. No advertisement or other descriptive printed material issued by the applicant or private label distributor with respect to this device shall recommend or imply that the device may be used for any use that is not included in the FDA approved labeling for the device. If the FDA approval order has restricted the sale, distribution and use of the device to prescription use in accordance with 21 CFR 801.109 and specified that this restriction is being imposed in accordance with the provisions of section 520(e) of the act under the authority of section 515(d)(1)(B)(ii) of the act, all advertisements and other descriptive printed material issued by the applicant or distributor with respect to the device shall include a brief statement of the intended uses of the device and relevant warnings, precautions, side effects and contraindications.

PREMARKET APPROVAL APPLICATION (PMA) SUPPLEMENT. Before making any change affecting the safety or effectiveness of the device, submit a PMA supplement for review and approval by FDA unless the change is of a type for which a "Special PMA Supplement-Changes Being Effected" is permitted under 21 CFR 814.39(d) or an alternate submission is permitted in accordance with 21 CFR 814.39(e). A PMA supplement or alternate submission shall comply with applicable requirements under 21 CFR 814.39 of the final rule for Premarket Approval of Medical Devices.

All situations which require a PMA supplement cannot be briefly summarized, please consult the PMA regulation for further guidance. The guidance provided below is only for several key instances.

A PMA supplement must be submitted when unanticipated adverse effects, increases in the incidence of anticipated adverse effects, or device failures necessitate a labeling, manufacturing, or device modification.

A PMA supplement must be submitted if the device is to be modified and the modified device should be subjected to animal or laboratory or clinical testing designed to determine if the modified device remains safe and effective.

A "Special PMA Supplement - Changes Being Effected" is limited to the labeling, quality control and manufacturing process changes specified under 21 CFR 814.39(d)(2). It allows for the addition of, but not the replacement of previously approved, quality control specifications and test methods. These changes may be implemented before FDA approval upon acknowledgment by FDA that the submission is being processed as a "Special PMA Supplement - Changes Being Effected." This acknowledgment is in addition to that issued by the PMA Document Mail Center for all PMA supplements submitted. This procedure is not applicable to changes in device design, composition, specifications, circuitry, software or energy source.

Alternate submissions permitted under 21 CFR 814.39(e) apply to changes that otherwise require approval of a PMA supplement before implementation of the change and include the use of a 30-day PMA supplement or annual postapproval report. FDA must have previously indicated in an advisory opinion to the affected industry or in correspondence with the applicant that the alternate submission is permitted for the change. Before such can occur, FDA and the PMA applicant(s) involved must agree upon any needed testing protocol, test results, reporting format, information to be reported, and the alternate submission to be used.

POSTAPPROVAL REPORTS. Continued approval of this PMA is contingent upon the submission of postapproval reports required under 21 CFR 814.84 at intervals of 1 year from the date of approval of the original PMA. Postapproval reports for supplements approved under the original PMA, if applicable, are to be included in the next and subsequent annual reports for the original PMA unless specified otherwise in the approval order for the PMA supplement. Two copies identified as "Annual Report" and bearing the applicable PMA reference number are to be submitted to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, Maryland 20850. The postapproval report shall indicate the beginning and ending date of the period covered by the report and shall include the following information required by 21 CFR 814.84:

(1) Identification of changes described in 21 CFR 814.39(a) and changes required to be reported to FDA under 21 CFR 814.39(b).

(2) Bibliography and summary of the following information not previously submitted as part of the PMA and that is known to or reasonably should be known to the applicant:

(a) unpublished reports of data from any clinical investigations or nonclinical laboratory studies involving the device or related devices ("related" devices include devices which are the same or substantially similar to the applicant's device); and

(b) reports in the scientific literature concerning the device.

If, after reviewing the bibliography and summary, FDA concludes that agency review of one or more of the above reports is required, the applicant shall submit two copies of each identified report when so notified by FDA.

ADVERSE REACTION AND DEVICE DEFECT REPORTING. As provided by 21 CFR 814.82(a)(9), FDA has determined that in order to provide continued reasonable assurance of the safety and effectiveness of the device, the applicant shall submit 3 copies of a written report identified, as applicable, as an "Adverse Reaction Report" or "Device Defect Report" to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, Maryland 20850 within 10 days after the applicant receives or has knowledge of information concerning:

(1) A mix-up of the device or its labeling with another article.

(2) Any adverse reaction, side effect, injury, toxicity, or sensitivity reaction that is attributable to the device and

(a) has not been addressed by the device's labeling or

(b) has been addressed by the device's labeling, but is occurring with unexpected severity or frequency.

(3) Any significant chemical, physical or other change or deterioration in the device or any failure of the device to meet the specifications established in the approved PMA that could not cause or contribute to death or serious injury but are not correctable by adjustments or other maintenance procedures described in the approved labeling. The report shall include a discussion of the applicant's assessment of the change, deterioration or failure and any proposed or implemented corrective action by the applicant. When such events are correctable by adjustments or other maintenance procedures described in the approved labeling, all such events known to the applicant shall be included in the Annual Report described under "Postapproval Reports" above unless specified otherwise in the conditions of approval to this PMA. This postapproval report shall appropriately categorize these events and include the number of reported and otherwise known instances of each category during the reporting period. Additional information regarding the events discussed above shall be submitted by the applicant when determined by FDA to be necessary to provide continued reasonable assurance of the safety and effectiveness of the device for its intended use.

REPORTING UNDER THE MEDICAL DEVICE REPORTING (MDR) REGULATION. The Medical Device Reporting (MDR) Regulation became effective on December 13, 1984. This regulation was replaced by the reporting requirements of the Safe Medical Devices Act of 1990 which became effective July 31, 1996 and requires that all manufacturers and importers of medical devices, including in vitro diagnostic devices, report to the FDA whenever they receive or otherwise become aware of information, from any source, that reasonably suggests that a device marketed by the manufacturer or importer:

- (1) May have caused or contributed to a death or serious injury; or
- (2) Has malfunctioned and such device or similar device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

The same events subject to reporting under the MDR Regulation may also be subject to the above "Adverse Reaction and Device Defect Reporting" requirements in the "Conditions of Approval" for this PMA. FDA has determined that such duplicative reporting is unnecessary. Whenever an event involving a device is subject to reporting under both the MDR Regulation and the "Conditions of Approval" for a PMA, the manufacturer shall submit the appropriate reports required by the MDR Regulation within the time frames as identified in 21 CFR 803.10(c) using FDA Form 3500A, i.e., 30 days after becoming aware of a reportable death, serious injury, or malfunction as described in 21 CFR 803.50 and 21 CFR 803.52 and 5 days after becoming aware that a reportable MDR event requires remedial action to prevent an unreasonable risk of substantial harm to the public health. The manufacturer is responsible for submitting a baseline report on FDA Form 3417 for a device when the device model is first reported under 21 CFR 803.50. This baseline report is to include the PMA reference number. Any written report and its envelope is to be specifically identified, e.g., "Manufacturer Report," "5-Day Report," "Baseline Report," etc. Any written report is to be submitted to:

Food and Drug Administration
Center for Devices and Radiological Health
Medical Device Reporting
PO Box 3002
Rockville, Maryland 20847-3002

Copies of the MDR Regulation (FOD # 336&1336) and FDA publications entitled "An Overview of the Medical Device Reporting Regulation" (FOD # 509) and "Medical Device Reporting for Manufacturers" (FOD #987) are available on the CDRH WWW Home Page. They are also available through CDRH's Fact-On-Demand (F-O-D) at

800-899-0381. Written requests for information can be made by sending a facsimile to CDRH's Division of Small Manufacturers Assistance (DSMA) at 301-443-8818.

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SUMMARY OF SAFETY AND EFFECTIVENESS DATA

I GENERAL INFORMATION

Device Generic Name: Sharps Needle Destruction Device.

Device Trade Name: Needlyzer™ The Needle Destroyer Model ND2

Applicant's Name and Address:

Healthcare Products Plus, Inc.
1006 Battery Lane
Nashville, Tennessee 37220

Premarket Approval Application Number: P960018

Date of Notice of Approval to the Applicant: JUL 16 1998

II INDICATIONS FOR USE

The Needlyzer™ is a mobile sharps needle destruction device that is intended to oxidize non-coated stainless steel needles immediately after use. The device will oxidize to the hub butterfly-type needles and all needles 16-30 gauge and 4-52 mm in length attached to a metal or plastic hub or a vacutainer. The device is intended to be used in hospitals and other healthcare facilities.

III CONTRAINDICATIONS

DO NOT use the Needlyzer™ ND2 in any potentially explosive environment, or where flammable gases or fluids are stored or are in use e.g., operating rooms, emergency rooms, etc. Using this device near flammable materials may cause an explosion or fire that could result in significant injuries.

DO NOT use the Needlyzer™ ND2 in those areas in which electrical life support, life sustaining or patient diagnostic equipment is in use because of the potential for electromagnetic interference.

IV WARNINGS AND PRECAUTIONS

The warnings and precautions can be found in the labeling for the Needlyzer™ both in the Instruction Booklet and on the device.

V DEVICE DESCRIPTION

The Needlyzer™ - The Needle Destroyer Model ND2 is a sharps needle destruction device used to destroy uncoated butterfly-type needles and 16-30 gauge needles attached to a syringe and vacutainer. The Needlyzer™ consists of two chrome zirconium copper electrodes, a rotating electrode wheel and a stationary electrode element. The needle is inserted into the needle entry opening and is guided between the two electrodes where a 2 volt current heats the needle to 1500°C to oxidize the needle. A knob next to the opening allows the user to adjust the gap between the electrodes according to the needle size. The rotating electrode is activated as the user approaches the device with the needle and interrupts an infrared eye beam sensor. A fan draws air in through the needle entry opening, across the electrodes and through a filter before being exhausted through the base of the unit. The residue of approximately 3000-5000 needles is collected in a disposable filter cartridge. The cartridge is covered with a plastic lid as it is removed from the device. The molding of the unit housing and cartridge are made of General Electric Company "Lexon" plastic, (hospital grade). The Model ND2 requires a 12 VDC 2.6 amp hours lead acid gel battery power source, measures 13.5 inches x 5 inches x 4.75 inches, and weighs 5 lbs 6 oz. The Model ND2 has a battery saving on/off switch and a red light that indicates low battery power and a green light to indicate that the unit is on. The Needlyzer™ may also be used mounted on the wall with a bracket. To neutralize the odor that may be produced during needle destruction, a few drops of Clean Air Fragrance may be added to the swing out tray at the exhaust port on the bottom of the unit. Accessories to the Needlyzer™ include Needlyzer™ Cartridges, Needlyzer™ Batteries, Needlyzer™Charger, Needlyzer™ Remote Charger and Needlyzer™ Clean Air Fragrance.

VI ALTERNATIVE PRACTICES AND PROCEDURES

The disposal of hypodermic needles is determined by regulations published in The Federal Register, issued Friday, December 6, 1991, Part II, Department of Labor, Occupational Safety and Health Administration, 29 CFR Part 1910.1030- "Occupational Exposure to Bloodborne Pathogens, Final Rule". The method of needle disposal discussed in the "Final Rule" states that sharps are to be placed in containers that are closeable, puncture resistant and leak proof. Needle destruction devices, other than this device, also are available for the disposal of sharps.

VII MARKETING HISTORY

Prior to 1993, a number of units were marketed in the United States, Canada and Europe. Those marketed in the United States were recalled after the FDA began actively regulating sharps containers. Approximately 1500 units have been purchased in Europe, Canada and Mexico. None of these units have been removed from the market due to concerns about safety and effectiveness.

VIII POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH

The Needlyzer™ does not have direct contact with the patient or the user when used as directed. There have been no adverse effects reported.

IX SUMMARY OF PRECLINICAL STUDIES

Note: The testing conducted with the electrically powered Model ND1 of the Needlyzer™ is applicable to the battery powered Model ND2 of the Needlyzer™.

Test for Emission of Toxic Fumes

Tests on a single electrically powered Model ND1 device were performed to determine the potential for emission of toxic fumes during operation of the Needlyzer™ unit.

Results: There were no organic materials above one part per million at the point of the exhaust following the destruction of 10 needles over 30 minutes. On the interior filter, 100 ppm of chromium, 334 ppm of iron and 9.2 ppm of nickel were recovered.

Conclusion: These levels of metals do not represent a health concern to persons operating the device.

Generation of Heat

A study was performed using a single electrically powered Model ND1 device to determine the amount of heat generated during destruction of stainless steel products SS# 301 and SS#304 by the Needlyzer™. A temperature of 2590° F must be attained to achieve oxidization.

Results and Conclusion: The oxidization process exceeds the minimum heat required for needle oxidization.

The heat dissipation characteristics in the interior and at the surface of the Needlyzer™ unit during the oxidization process were studied using a single electrically powered Model ND1 device.

Results: The air temperature inside the device did not exceed 108° F. The air flow helps maintain the interior temperature at 108°C or below during needle destruction.

Conclusion: The results provide reasonable assurance that the temperature inside the device during needle destruction by the Needlyzer™ does not present an unreasonable risk of thermal burns to the user because the temperature does not exceed 108°F.

Formation of Sparks

A study was conducted with a single electrically powered ND1 device to evaluate the risk of fire during needle destruction by the Needlyzer™ in the presence of flammable liquids.

Results: Polypropyl alcohol, butane lighter fluid and gasoline did not ignite when tissues and paper towels soaked in the fluids were placed over the needle aperture during needle destruction by the Needlyzer™.

A study was conducted with a single electrically powered Model ND1 device to evaluate the potential reaction when needles filled with flammable substances, such as alcohol and toluene, are destroyed with the Needlyzer™.

Results: Unburned alcohol and toluene were found in the cartridge after test needles were expended.

Conclusion: The results provide reasonable assurance that the sparks generated at the electrodes during needle destruction by the Needlyzer™ do not present an unreasonable risk of thermal burns to the user or fire in the presence of alcohol, toluene, lighter fluid, or gasoline during needle destruction. However, the Needlyzer™ should be contraindicated for use in any potentially explosive environment where flammable gases or liquids are used or stored.

Liquid Spill and Drop Testing

Tests were performed with a single battery powered Model ND2 device to evaluate the electrical safety of the Needlyzer™ following a liquid spill in or on the device or a drop onto a hard surface.

Results: Spillage testing and drop testing were completed in accordance with C.S.A. Laboratory standards, UL 544 standards and IEC 601-1 standards.

Conclusions: The unit successfully passed all requirements of the standards for spill and drop testing.

Formation of Infectious Aerosols

Tests were performed with a single battery powered Model ND2 device to evaluate the Needlyzer™ for its potential to disseminate aerosols.

Results of study 1: Except for one case in which 130 colony forming units of *M. smegmatis* were recovered from 55 liters of air, no colonies were recovered from air sampled above the needle aperture or at the exhaust port when needles inoculated with *M. smegmatis* or *B. subtilis* were destroyed by the Needlyzer™. However, organisms were

recovered from the inside surfaces of the air sampling device and the deck of the device. Since the plunger was not depressed during this test, fluid may have been expelled into the device prior to and during needle destruction. Therefore, additional testing was conducted.

Results of study 2: Except for one sentinel agar plate in which 1 colony of *M. smegmatis* was recovered, no colonies were recovered in agar plates placed on, around and under the device during destruction of twenty 18 gauge needles inoculated with *M. smegmatis* or *B. subtilis*. There was no appreciable difference in the effectiveness of the unit whether the cartridge was full or empty.

Conclusion: The Needlyzer™ does not appear to generate aerosols when needles are destroyed according to the directions for use, since very few test organisms were recovered during destruction of inoculated needles. The labeling instructs the user to expel all liquids from the syringe prior to needle destruction.

Microbiological Testing of the Needle Residue

Tests were performed with a single electrically powered Model ND1 device to determine the extent of kill of microorganisms on inoculated needles during needle destruction with the Needlyzer™.

Results: 260 needles ranging from 16 gauge to 30 gauge were inoculated with one of the following organisms: *Pseudomonas aeruginosa*, *Streptococcus faecalis*, *Bacillus subtilis*, *Bacillus stearothermophilus*, *Staphylococcus aureus*, *Mycobacterium terrae*, *Candida albicans*, Poliovirus, and *Aspergillus fumigatus*. The needles were destroyed by the Needlyzer™ and the residue was cultured on agar plates.

Results: No viable organisms/viral particles were recovered from the needle residue in the cartridge.

Conclusion: The Needlyzer™ appears to destroy vial particles and microorganisms on needles during destruction of needles. These data do not imply that the residue is sterile.

Electrical Safety

A study was conducted with a single battery powered Model ND2 device to test the Needlyzer™ for electrical safety.

Results: The unit passed the applicable requirements of the CSA (Laboratory Standard) UL 544 (Medical and Laboratory Standard) and IEC 601-1.

Conclusion: The Needlyzer™ does not appear to present an electrical hazard to the user during needle destruction.

Testing for Electromagnetic Interference

Studies were conducted with a single battery powered Model ND2 device to evaluate the Needlyzer™ for electromagnetic emissions.

Results: Testing showed that no ambient noise was generated except at the start of the oxidization process (about ½ second at 190 MHz).

Conclusion: The Needlyzer™ does not meet the guidelines for electromagnetic compatibility under all conditions. Therefore, the Needlyzer™ should be contraindicated for use in those areas in which electrical life support, life sustaining or patient diagnostic equipment is in use.

X SUMMARY OF CLINICAL STUDIES

The objective of the clinical studies was to determine the effectiveness of the Needlyzer™ when used by a broad group of professions under various working conditions using various types of apparatus and employing 16-30 gauge needles and butterfly needles. One study was conducted with the electrically powered model of the Needlyzer™, Model ND1, with 20 and 30 gauge needles, while a second study was conducted with the battery powered model of the Needlyzer™, Model ND2, to evaluate 16 and 18 gauge needles and the needle gauge adjustment control knob.

Study Design

The criteria for the successful use of the device were:

- (a) Did the needle oxidize to the hub?
- (b) Was the Needlyzer™ preferable to conventional sharps containers?
- (c) Did the Needlyzer™ fail to perform as expected?
- (d) Were there any accidental needle sticks attributable to the Needlyzer™?
- (e) Could the Needlyzer™ be conveniently located.

During the initial clinical study, 118 facilities participated with a total of 479 professional subjects. The total number of needles oxidized during the study exceeded 148,000 of which 2127 were butterfly needles and 18,322 were 20 and 30 gauge vacutainer needles. The tests took place in County and State Health Departments, Allergy Clinics, Laboratories, Nursing Homes, Dental Clinics, Veterinarian Clinics, Ambulatory Clinics, AIDS Clinics, Hospital Wards/Emergency Rooms, Corporate Infirmaries, Correctional Facilities, Military Bases, Pediatric Clinics and Anesthesiologists.

In the second study, 2 units of the Needlyzer™ were evaluated in an OB/GYN Anesthesiology Department. A total of sixty 16 gauge needles, fifty 18 gauge needles and ten butterfly needles were evaluated.

Results

Initial study: Out of the more than 148,000 needles destroyed, there were five failures of the product to operate as expected. Four failures were a result of jamming. Following a pause, insertion of the needle proceeded with needle destruction. The other failure was due to no arcing because of a worn out electrode.

There were no adverse observations during the study. There were no accidental needle sticks reported in the questionnaire as a result of the use of the Needlyzer™. Three accidental needle sticks were reported in correctional centers during the test period using conventional methods of needle containment.

The Needlyzer™ was preferred over current methods of needle disposal in 98 of the 117 facilities in which testing was conducted. Housekeepers, waste haulers, veterinarians, allergists, laboratory technicians, and most other physicians and surgeons found the device acceptable. Personnel in pediatric clinics, hospital/emergency facilities, and dental clinics were more equally divided in their preference.

Second study: Out of the 120 needles destroyed, four unspecified failures were reported. During the test period, no accidental needle sticks were reported as a result of use of the Needlyzer™ or using conventional methods of needle containment. The users rated the labeling as excellent and participating physicians rated the device favorably.

Conclusion

The device performs as expected but some users may prefer alternative needle disposal devices.

XI SUMMARY CONCLUSION DRAWN FROM THE STUDIES

The pre-clinical and clinical testing provides reasonable assurance of safety and effectiveness of the device when used in accordance with the instructions for use.

XII PANEL RECOMMENDATION

Based on the regulatory discretion provided in section 515(c)(2) of the Food, Drug and Cosmetic Act as amended by the Safe Medical Devices Act of 1990, this PMA was not referred to the General Hospital and Personal Uses Panel, a Food and Drug Administration (FDA) advisory committee, for review and recommendation.

XIII CDRH DECISION

Based on the data submitted, CDRH has determined that there is reasonable assurance that the Needlyzer™ The Needle Destroyer Model ND2 needle destruction device is safe and effective for its intended use. FDA has determined that a preapproval GMP inspection will not be required. However, the device is still subject to the provisions of the GMP regulation (21 CFR Part 820) and will be subject to routine GMP inspections following approval. CDRH issued an approval order on JUL 16 1998.

XIV APPROVAL SPECIFICATIONS

Directions for use: See the labeling.

Hazards to Health from Use of the Device: See "Indications," "Warnings," and "Precautions" in the labeling.

Postapproval Requirements and Restrictions: See approval order.

XV REFERENCES

Guidance on the Content and Format of Premarket Approval Applications [PMA] for Sharps Needle Destruction Devices, Draft Document, February 11, 1997 Draft.

LABELING

Device Description

The Needlyzer™ - The Needle Destroyer is a sharps needle destruction device used to destroy uncoated butterfly-type needles and 16-30 gauge needles attached to a syringe and vacutainer. The Needlyzer™ consists of two chrome zirconium copper electrodes, a rotating electrode wheel and a stationary electrode element. A Dial-A-Matic knob next to the aperture allows the user to adjust the gap between the electrodes according to the needle size. The residue of approximately 3000-5000 needles is collected in a disposable filter cartridge. The cartridge is covered as it is removed from the device. The Model ND2 requires a 12 VDC 2.6 amp hours lead acid gel battery power source, measures 13.5 inches x 5 inches x 4.75 inches, and weighs 5 lbs 6 oz. The Needlyzer™ may also be used mounted on the wall with a bracket. To neutralize the odor that may be produced during needle destruction, a few drops of Clean Air Fragrance may be added to the swing out tray at the exhaust port on the bottom of the unit. Accessories to the Needlyzer™ include Needlyzer™ Cartridges, Needlyzer™ Batteries, Needlyzer™ Charger, Needlyzer™ Remote Charger and Needlyzer™ Clean Air Fragrance.

Indications for Use

The Needlyzer™ is a mobile sharps needle destruction device that is intended to oxidize non-coated stainless steel needles immediately after use. The device will oxidize to the hub butterfly-type needles and all needles 16-30 gauge and 4-52 mm in length attached to a metal or plastic hub or a vacutainer. The device is intended to be used in hospitals and other healthcare facilities.

Contraindications

DO NOT use the Needlyzer™ ND2 in any potentially explosive environment, or where flammable gases or fluids are stored or are in use e.g., operating rooms, emergency rooms, etc. Using this device near flammable materials may cause an explosion or fire that could result in significant injuries.

DO NOT use the Needlyzer™ ND2 in those areas in which electrical life support, life sustaining or patient diagnostic equipment is in use because of the potential for electromagnetic interference.

Warnings

The device should not be used to destroy objects other than stainless steel hypodermic needles because the safety and effectiveness of using the device with other objects has not been established.

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Precautions

DO NOT evacuate syringe contents into the device. Allowing fluids or moisture into the device could contaminate the surrounding environment during needle destruction and could damage or corrode electronics.

When operating this device follow universal safety precautions, including OSHA guidelines, when handling needles and other biohazardous materials. Operators should consider waste inside cartridge as contaminated waste and should always wear protective gloves when oxidizing a needle or handling the cartridge.

If the needle gets stuck and the oxidization process stops, lift the syringe (to relieve pressure) wait three seconds and restart the process.

Since the filter system has a maximum effective cycle, do not reuse the Needlyzer™ cartridges. The safe and effective reuse of the cartridge has not been established.

Electrical safety features are designed for the intended use of this product. Use of this device for any other purpose than those intended may cause electrical malfunction and permanent damage to the device.

Do not turn the unit upside down with the cartridge inserted. Keep this device upright at all times using the handle to transport it. When transporting the device other than by using the handle, remove the cartridge. The needle residue has magnetic properties which may cause the unit to cease operating.

Do not attempt to open the unit (other than cartridge and battery removal and replacement) or place hands within unit. The cartridge may contain foreign material that is contaminated. Dispose of the cartridge according to institutional procedures governing hazardous waste.

Do not attempt to destroy needles after red "low battery" light appears. Continued use will cause excessive wear to the Needlyzer™ internal components and decrease the life of the battery. Only oxidize needles when the green "Float" light appears.

Do not operate unit before reading Operating Instructions, including "Removing Cartridge," "Replacing Cartridge," "Removing Battery," "Replacing Battery," "Charging Battery," and "Operating Charger," in this booklet.

Use only genuine Needlyzer™ Cartridges, Needlyzer™ Batteries, Needlyzer™ Charger, Needlyzer™ Remote Charger, and Needlyzer™ Clean Air Fragrance with this unit. Do not attempt to charge any other battery with the Needlyzer™ charger. It has been set for a specific ohms rating. The safety and effectiveness of the Needlyzer™ has not been established with any accessories other than those identified above.

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Maintain full charge on Needlyzer™ batteries at all times. The charger should be connected to the unit at all times except when being transported.

Directions for Use

NEEDLE DESTRUCTION

When handling or oxidizing a needle or when removing the cartridge always wear protective gloves as you would with any other sharps container.

1. Turn "On/Off" switch at back of unit to the "on" position. If the charger is connected to the power source, leave the switch in the "on" position.
2. Make sure that "ready light" is glowing green. The device is now ready for use. If the green "ready light" is not on:
 - a) Make sure that switch on back is in the "on" position.
 - b) Make sure battery is correctly installed.
 - c) Make sure cartridge is pressed into position.
 - d) Make sure that there is nothing blocking the electric eye.
3. Set the "Dial-A-Matic" needle gauge control to the size of the needle to be destroyed. Failure to do so will greatly reduce the effectiveness of the device and cause excessive wear.
4. DO NOT evacuate syringe contents into the device. Allowing fluids or moisture into the device could contaminate the surrounding environment during needle destruction and could damage or corrode electronics.
5. Hold the syringe between the thumb, index and middle fingers and bring the syringe to the aperture. This will automatically make the device ready for the destruction process. Best results are achieved by positioning your fingers directly in front of the sensor's "eye." (See Figure 2)
6. After the needle has been oxidized, remove the syringe and discard it immediately into the nearest designated biohazard bag or hard plastic waste container. Allow a minimum of 2 seconds between oxidizing needles.
7. If unit jams or fails to complete the oxidization cycle to the hub, slightly lift the needle, relieving pressure. Wait three seconds and when the motor is reactivated (whirring sound), press needle down again and twist. If the unit fails to complete the oxidization cycle to the hub, deposit the remaining needle and attached syringe in an alternate sharps container closest to the point of use.

8. When the unit is not connected to the charger and when not in use, turn the "On/Off" switch to the "off" position to save battery power. When the unit is connected to the charger leave the "On/Off" switch in the "on" position at all times.
9. The power is automatically disconnected when the cartridge is removed, when the on/off switch (back of unit) is off, or battery is removed. The 'power on/ready' indicator (green light) and the 'low battery power' indicator (red light) will not glow.
10. To disconnect the device, remove the plug from the charger.
11. When not in use for long periods, maintain a maximum charge by keeping the charger connected to the unit. The Needlyzer™ charger will not overcharge the battery. The device may be continuously connected to the charge.
12. Sparks may be emitted during the oxidization process. When used in the indicated environment, this does not present a danger to the operator. If the spark shields appear to be damaged, the device should be returned to the manufacturer or the service office should be contacted.

This device is contraindicated for use in any potentially explosive environment where flammable substances are stored or used. The sparking may cause an explosion or fire that could result in personal injury or the destruction of property.

REMOVING NEEDLE WASTE BY REMOVING CARTRIDGE

1. The cartridge will hold between 2,000 to 5,000 oxidized hypodermic needles. The filter is effective for each fill. Replace filled cartridges. DO NOT REUSE.
2. To examine the volume of waste periodically, partially pull out the cartridge and observe for fullness through the clear plastic top. (See Figure 2) This disconnects the power and the green "Ready Light" will go out.
3. When the cartridge is full, it should be removed to a central holding area for waste collection.
4. Using both hands, place the left hand on top of the unit (to steady it). Locate the pull handle on the face of the cartridge. Using fingers of right hand, pull cartridge slowly forward with even pressure until cartridge is fully removed. (Figure 2)
5. Operators should consider waste inside cartridge as contaminated waste and should always wear protective gloves when handling the cartridge.
6. After removal, the cartridge should be covered by the clear plastic ribbed lid and locked. (see Figure 3)

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7. If the lid failed to cover the cartridge completely on removal, pull cartridge cover to closing position over table and snap closed. (Figure 3)

REPLACING THE CARTRIDGE

1. Remove the wrap protecting the new cartridge.
2. Place the cartridge in position and carefully push it into the unit until it cannot go any further and fits snugly. The face of the device and the cartridge should be aligned.
3. Make sure the "On/Off" switch on the back of the unit is in the "on" position.
4. Make sure that the green "Ready Light" is on. This indicates that the cartridge is properly in place and in the "locked" position.
5. Place your hand in front of the electric eye, next to the green "Ready Light." The motor should start, indicating that the unit is ready to use.

CLEANING THE NEEDLYZER™

1. Always use protective gloves and other protective devices during cleaning.
2. Dampen a cleaning cloth with a disinfectant. Follow institutional policy on recommended disinfectant for wiping work counters and instruments or a commercial chlorine cleaning agent, a solution of hydrogen peroxide or isopropyl alcohol.
3. Clean around the needle aperture with a dampened cloth. Do not use excessive amounts of disinfectant.
4. Do not immerse the device in water or any liquid. Should that situation occur accidentally, unplug the charger at the power source, lift the device out of the liquid, remove the cartridge and battery and set the device on its end until dried. When dry install a new cartridge and a charged battery.

BATTERY CHARGER OPERATION

1. If the red "Low Battery" light appears, finish oxidizing the needle currently being destroyed but do not continue with additional needles.
2. The device will not efficiently oxidize additional needles until the battery is charged or replaced with a charged battery.

CHARGING AND MAINTAINING A BATTERY

1. Connect the three prong charge into a grounded wall socket. (110 VAC)
2. Connect the barrel attached to the 12 volt line cord coming from the charger to the adapter plug located in the back of the Needlyzer™ where indicated by the label.
3. The charger may be connected to the Needlyzer™ permanently, if so desired by the operator. The device cannot be over charged.
4. When the charger is properly connected to the power source and the Needlyzer™, the charger indicator light will glow red or green. Red indicates a short or faulty battery condition. Green indicates that the charger is in the slow charge (Float) mode plugged into an outlet ready for use.
5. A low battery will require time to recharge. Do not attempt to oxidize needles until the green "Float" light appears.
6. When the green "Float" light appears, the operator may disengage the Needlyzer™ from the charger by removing the barrel connector from the device.
7. When the Needlyzer™ unit is connected to the charger and the green "Float" light has appeared, the red "Fast Charge" light may appear during or immediately following the oxidization process. This is normal.

BATTERY INSTALLATION

1. For ease of operation, place back of unit over edge of table so that the battery door may be pushed down easily.
2. To install a Needlyzer™ Battery, slide the battery cover door down until it is free from the unit, as indicated in Figure 8.
3. Hold the unit firmly with the left hand and pull the ribbon forward making sure that it lies in the center of the slot at the bottom.
4. Pull ribbon to full outward position and make sure that the ribbon is showing at the bottom center of the battery before installing. Following the label instructions, push the Needlyzer™ Battery into the slot as the arrow directs.
5. Insert the slide cover in place, pushing up through the side slots.

BATTERY REMOVAL

1. For ease of operation, place back of unit over edge of table so that the battery door may be pushed down easily.
2. To remove the Needlyzer™ Battery, slide the battery cover door down until it is free of the unit as indicated on Figure 8.
3. Hold the unit firmly with your left hand. With your right hand, slowly pull ribbon forward until the Needlyzer™ Battery partially slides out. (See Figure 9)
4. With right hand, grasp the Needlyzer™ Battery and pull it directly out of the device as shown in Figure 9.
5. If the ribbon does not appear, tilt unit upward and gently tap until battery slides outward.

SUPPLEMENTARY NEEDLYZER™ BATTERY CHARGER

The supplementary Needlyzer™ Battery Charger is available in two models, Model B1 for One Battery and Model B2 for Two Batteries. The Needlyzer™ Battery Charger cannot overcharge a battery. The device always selects the battery requiring the least charge first to minimize the time required to have a fully charged battery. When the first selected battery is charged, it automatically selects the next battery in line.

HOW TO OPERATE THE NEEDLYZER™ REMOTE RECHARGER

1. Connect recharger to 110 VAC 60 Hz grounded power source. Place battery requiring charge on ribbon in empty (or either) channel.
2. Push battery into channel until it stops.
3. If required, push second, third and fourth batteries in empty channels.
4. "Charging Light" will glow red as battery is being charged.
5. "Ready Light" will glow green over each battery channel when its battery is charged.
6. The battery may be removed as required.
7. To remove a charged battery, pull the ribbon forward until the battery may be gripped by the right hand.
8. Pull the battery directly out of the channel.

9. The Needlyzer™ Battery Charger may continue to be plugged into the power source or removed.