SUMMARY OF SAFETY AND EFFECTIVENESS DATA

I. GENERAL INFORMATION

Device Generic Name:	Needle Destruction Device
Device Trade Name:	NeedleZap™
Applicant Name and Address:	E Med Future, Inc. Robert Ochsendorf, President 794 Morrison Road Columbus, Ohio 43230
PMA Application #:	P010065
Date of Good Manufacturing Inspection:	February 7 and 13, 2003
Date of Approval:	March 14, 2003

II. INDICATIONS FOR USE

The NeedleZap™ product is a portable needle destruction device that is intended for use by health care professionals to destroy previously used aluminum and stainless steel needles (gauges 16-30, ¾-2 inches in length) attached to syringes. The NeedleZap™ product is intended for use in health care facilities and treatment settings.

III. CONTRAINDICATIONS

A. DO NOT USE THIS DEVICE NEAR FLAMMABLE LIQUIDS, GASES, OXYGEN, OPERATING ROOMS, OR EXPLOSIVES. NeedleZap™ can produce minor sparking which could create the risk of explosion or fire in this type of environment.

B. DO NOT DESTROY NEEDLES THAT CONTAIN EXPLOSIVE OR RADIOACTIVE MATERIALS.

IV. WARNINGS AND PRECAUTIONS

A. DO NOT use two hands to operate the unit. It is designed for simple one-handed use to avoid your other hand becoming a target.

B. DO NOT use this product near a sink, washtub or other location where it could be immersed or subjected to high moisture.

C. DO NOT open the unit. Should your product require service, return it to the manufacturer.

D. DO NOT insert needle into the charger terminal (*see* Figure B below).

E. DO NOT operate while the unit is connected to charger. NeedleZap™ is designed as a portable device.

F. Should your device ever malfunction, maintain your level of caution and dispose of any remaining portion of the hypodermic needle according to proper disposal method regulations in your area.

G. As with any appliance or tool, keep out of reach of children.

V. DEVICE DESCRIPTION

The NeedleZap™ product is designed for one-hand use when destroying 16-30 gauge needles, ¾-2 inches in length. The needle is destroyed by placing it vertically into the opening on top of the NeedleZap™ and then is gently rotated for 2-4 seconds to destroy the tip down the entire length to the hub. The NeedleZap™ portable needle destruction device operates from a battery pack consisting of two (2) 2V D-size rechargeable batteries. When a needle is inserted in the opening, it delivers 2.5A of current between two angled copper electrodes. Inside the product is a magnetic stainless steel clean-out tray that collects the debris from the destroyed needles. NeedleZap™ can be used to destroy 50-100 needles before the batteries need to be recharged using the NeedleZap™ 6V Charger that comes with the unit. The recharging process takes three (3) to four (4) hours.

The product measures 3" x 4" x 2" and weighs 1.4 lb. The housing is made of ABS flame-retardant plastic, and four rubber feet secure the unit from moving while placed on a flat surface.

VI. ALTERNATIVE PRACTICES AND PROCEDURES

The proper disposal of sharps is subject to federal Occupational Safety and Health Administration ("OSHA") regulations. The final rule, "Occupational Exposure to Bloodborne Pathogens" at 29 C.F.R. § 1910.1030, states that sharps are to be placed in containers that are closeable, puncture-resistant, and leak-proof.

VII. MARKETING HISTORY

Since May, 2001, the applicant has marketed NeedleZap™ exclusively to veterinarians and to law enforcement personnel. The product is a tool designed to complement existing methods of sharps disposal, including as puncture-resistant sharps containers, and the applicant has not marketed this product for destruction of needles used in treatment settings and clinical laboratories. There have been no reported accidental needlesticks associated with the use of this product for law enforcement or veterinary use.

VIII. POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH

There are no anticipated adverse effects on patient health from the use of NeedleZap™. No adverse effects were reported during the investigator studies. Failure of the device to destroy the needle puts the user at no greater risk than would be encountered with no use of needle destruction device. Failure of the device to completely destroy the needle still results in a blunted and completely sealed needle tip.

IX. SUMMARY OF NON-CLINICAL LABORATORY STUDIES

Formation of Infectious Aerosols and Microbiological Testing

Testing was performed with 150 contaminated needles using a known inoculum of *B. stearothermophilus* to determine whether infectious aerosols were generated during the operation of NeedleZap™.

Results: There were no culturable microorganisms recovered from the collection plates placed around the device.

Conclusion: These results reveal that, under these test conditions, there is no evidence of bioaerosols formation after needle incineration by NeedleZap™. The labeling instructs to dispose of the needles and waste as biohazardous waste.

Test for Emissions of Toxic Fumes

Testing was performed using NIOSH test methods to determine if the destruction of 25 needles using NeedleZap™ produced toxic fumes.

Results: An independent laboratory report concluded that the vapors produced by the destruction of needles were not considered hazardous in all tests performed.

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

Generation of Heat

To determine the heat generation from NeedleZap™ when used in accordance with the labeling, testing was performed during the destruction of 20 gauge, 1¼ inch needles.

Results: The testing revealed external temperatures did not exceed 35ºC and the internal temperature was 33ºC during needle destruction.

Conclusion: No significant heating occurs after continuous use of NeedleZap™. These findings do not exceed the UL 2601-1 test standard.

Generation of Noise

To determine the noise generation from NeedleZap™ when used in accordance with the labeling, three attributes were tested during the destruction of 16-30 gauge, ¾-2 inch needles: (1) OSHA Hearing Conservation 80 dB Threshold; (2) OSHA Noise Compliance 90 dB Threshold; and (3) IEC Noise Monitoring, Raw Data Measurement.

Results: The testing revealed a minimum change in noise and may not be normally detectable.

Conclusion: This device does not generate excessive noise.

Formation of Sparks

The sparking observed inside NeedleZap™ is not uncommon when needles are destroyed. The fire risk has been further reduced by the use of two (2) D-size rechargeable batteries protected by a 30A circuit breaker. The labeling instructions contain the following contraindications for use of NeedleZap™

- DO NOT USE THIS DEVICE NEAR FLAMMABLE LIQUIDS, GASES, OXYGEN, OPERATING ROOMS, OR EXPLOSIVES. NeedleZap™ can produce minor sparking which could create the risk of explosion or fire in this type of environment.
- DO NOT DESTROY NEEDLES THAT CONTAIN EXPLOSIVE OR RADIOACTIVE MATERIALS.

In addition, there is a label with the following CAUTION near the needle entry point:

CAUTION
Do Not Operate
In the presence of flammable liquids,
vapors, operating rooms,
Or in the presence of elevated Oxygen
Levels
Some Sparking Will Occur

Results of the clinical studies did not report any problems associated with sparks.

Conclusion: NeedleZap™ should be contraindicated for use in any potentially explosive environment where flammable gases or liquids are used or stored.

Completeness of Destruction of Needles and Simulated Use

Simulated use testing was completed with 25 units of NeedleZap™ used to destroy 16-30 gauge, ¾ -2 inch needles. The criteria for the testing were the following:

a. PASS – needle completely destroyed from the tip to the hub OR needle burned completely to the hub with a tiny rounded stub with the sharp disabled
b. FAIL – needle partially destroyed and the sharp intact

Results: All 2,000 needles tested met the passing test criteria; either the needles were completely destroyed or the sharps were disabled.

Conclusion: The NeedleZap™ device can successfully destroy 16-30 gauge ¾-2 inch needles.

Stability

NeedleZap™ is noted to have 4 rubber feet and a low squat appearance. The applicant provided independent testing to demonstrate that the device remained stable and could withstand being dropped short distances.

Conclusion: NeedleZap™ is a stable device during normal use.

Cleaning

A cleaning study of the exterior of NeedleZap™ was conducted that included 20 trials of two common hospital cleaning agents. Egg white material was applied to cover the top of device to present visible soil. The device then was cleaned with the recommended cleaning agents. The firm also provided detailed cleaning instructions using standard precautions.

Results: The cleaning agents were able to remove visible evidence of soil without visible degradation of the surface of the device.

Conclusion: Visible soil can be successfully removed from the exterior of NeedleZap™ with the cleaning agent and the steps provided in the labeling.

Electrical Safety

An independent firm tested the electrical safety of NeedleZap™ and found it to be compliant with the applicable requirements of UL 2601-1 and EN 60601-1. The product is powered by two (2) rechargeable batteries connected in series and has a nominal 4.5V output. The risk of electrical shock to the user is limited because the device is to be used on battery.

To test for EMC compatibility, the applicant supplied independent testing with the charger connected to the device.

Results: NeedleZap™ is within the requirements for UL and conducted and radiated emissions testing. In addition, there were no reports of electrical shock during the clinical studies.

Conclusion: The results of testing NeedleZap™ during needle destruction demonstrate that the device does not represent an electrical hazard to the user or the clinical settings tested.

X. SUMMARY OF INVESTIGATOR STUDIES

Objective: To demonstrate that NeedleZap™ can be used safely and effectively by health care professionals and in health care facilities to destroy previously used aluminum and stainless steel needles attached to syringes.

Study Design #1: A total of seven investigators, all health care professionals, participated in this study. Each investigator was provided a NeedleZap™ unit for destruction of their used syringe needles (gauges 21-30, 1-2 inches in length), and was instructed to read the labeling before using the product. For a period of one month, each investigator was asked to complete a log that would provide information on the use of the product.

Results #1: The investigators reported a total of 720 needle destruction attempts. In every case, the needle destruction rate was 100%. One investigator reported that a small "stub" remained on each unit. No adverse events were reported.

Study Design #2: Testing was conducted at a hospital and a nursing home. Each investigator was provided a NeedleZap™ unit for destruction of syringe needles (gauges 16-30, ¾-2 inches in length), and was instructed to read the labeling before using the product. Each investigator was asked to complete a log that would provide information on the use of the product. Needle destruction was evaluated on a "0" (needle unaffected) to "3" (needle disable) scale.

Results #2: The investigators reported a total of 164 needle destruction attempts. The average burn grade was 2.65. No adverse events were reported.

XI. CONCLUSIONS DRAWN FROM THE STUDIES

The data from these studies provide reasonable assurance of safety and effectiveness of the product when used as intended and in accordance with the labeling.

Potential adverse effects have been assessed in the design of the product. No adverse events were reported during the clinical studies, or as a result of use for law enforcement or veterinary purposes.

XII. PANEL RECOMMENDATION

Based on the regulatory discretion provided in Section 515(c)(2) of the Federal 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, an FDA advisory committee, for review and recommendation.

XIII. CDRH DECISION

Based on the data submitted, CDRH has determined that there is reasonable assurance that NeedleZap™ is safe and effective for its intended use. CDRH issued an approval order on March 14, 2003.

The applicant's manufacturing facility was inspected on February 7 and 13, 2003 and found to be in compliance.

XIV. APPROVAL SPECIFICATIONS

Directions for Use: See the labeling.

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

Post-Approval Requirements and Restrictions: See approval order.