DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Memorandum

P970036

Date SEP 26 1997

From Director, Office of Device Evaluation (HFZ-400)
Center for Devices and Radiological Health (CDRH)

Subject Premarket Approval of NIC Limited's
NiC1800 Needle Disposal System - ACTION

To The Director, CDRH
ORA ____

ISSUE. Publication of a notice announcing approval of the subject PMA.

FACTS. Tab A contains a FEDERAL REGISTER notice announcing:

(1) a premarket approval order for the above referenced medical device (Tab B); and

(2) the availability of a summary of safety and effectiveness data for the device (Tab C).

RECOMMENDATION. I recommend that the notice be signed and published.

Susan Alpert, Ph.D., M.D.

Attachments
Tab A - Notice
Tab B - Order
Tab C - S & E Summary

DECISION

Approved ___ Disapproved ___ Date _____

Prepared by PFox, CDRH, HFZ-480, 9/25/97, 443-8913

DEPARTMENT OF HEALTH AND HUMAN SERVICES

DRAFT

Food and Drug Administration

[DOCKET NO. _____]

NIC Limited; Premarket Approval of NiC1800 Needle Disposal System

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application submitted by NIC Limited, Honolulu, HI, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of NiC1800 Needle Disposal System. FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of September 26, 1997, of the approval of the application.

DATES: Petitions for administrative review by (insert date 30 days after date of publication in the FEDERAL REGISTER).

ADDRESSES: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Chiu Lin,

Center for Devices and Radiological Health (HFZ-480),

Food and Drug Administration,

9200 Corporate Blvd.,

Rockville, MD 20850,

301-443-8913

SUPPLEMENTARY INFORMATION: On August 8, 1997, NIC Limited, Honolulu, HI 96812, submitted to CDRH an application for premarket approval of NiC1800 Needle Disposal System. The device is a needle destruction device and is indicated for the disposal of standard plastic syringe-mounted hypodermic needles (19 through 28 gauge, up to 2 inches in length) in patient treatment and clinical laboratory settings.

In accordance with the provisions of section 515(c)(2) of the act (21 U.S.C. 360e(c)(2)) as amended by the Safe Medical Devices Act of 1990, this PMA was not referred to the General Hospital and Personal Uses Panel of the Medical Devices Advisory Committee, an FDA advisory committee, for review and recommendation.

On September 26, 1997, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

Opportunity for Administrative Review

Section 515(d)(3) of the act authorizes any interested person to petition, under section 515(g) of the act, for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under 21 CFR part 12 of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under 21 CFR 10.33(b). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the FEDERAL REGISTER. If FDA grants the petition, the notice will state the issue to be reviewed, the form of the review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before (insert date 30 days after date of publication in the FEDERAL REGISTER), file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified

with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: _____.

_____

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

SEP 26 1997

NIC Limited
C/O Sheila Pickering, Ph.D.
Regulatory Consultant
320 Fairway Drive
Half Moon Bay, California 94019

Re: P970036
NiC1800 Needle Disposal System
Filed: August 8, 1997
Amended: September 15, 1997

Dear Dr. Pickering:

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 NiC1800 Needle Disposal System. This device is indicated for the disposal of standard plastic syringe-mounted hypodermic needles (19 gauge through 28 gauge, up to 2 inches in length) in patient treatment and clinical laboratory settings. 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 publish a notice of its decision to approve your PMA in the FEDERAL REGISTER. The notice will state that a summary of the safety and effectiveness data upon which the approval is based is available to the public upon request. Within 30 days of publication of the notice of approval in the FEDERAL REGISTER, any interested person may seek review of this decision by requesting an opportunity for administrative review, either through a hearing or review by an independent advisory committee, under section 515(g) of the Federal Food, Drug, and Cosmetic Act (the act).

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.

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 Ms. Patricia Fox at (301) 443-8913.

Sincerely yours,

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

Enclosure

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 mixup 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, and requires that all manufacturers and importers of medical devices, including in vitro diagnostic devices, report to FDA whenever they receive or otherwise became aware of information that reasonably suggests that one of its marketed devices

(1) may have caused or contributed to a death or serious injury or

(2) has malfunctioned and that the device or any other 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 this PMA, you shall submit the appropriate reports required by the MDR Regulation and identified with the PMA reference number to the following office:

Division of Surveillance Systems (HFZ-531)
Center for Devices and Radiological Health
Food and Drug Administration
1350 Piccard Drive, 340
Rockville, Maryland 20850
Telephone (301) 594-2735

Events included in periodic reports to the PMA that have also been reported under the MDR Regulation must be so identified in the periodic report to the PMA to prevent duplicative entry into FDA information systems.

Copies of the MDR Regulation and an FDA publication entitled, "An Overview of the Medical Device Reporting Regulation," are available by written request to the address below or by telephoning 1-800-638-2041.

Division of Small Manufacturers Assistance (HFZ-220)
Center for Devices and Radiological Health
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

SUMMARY OF SAFETY AND EFFECTIVENESS DATA

I. GENERAL INFORMATION

Device Generic Name: Sharps Needle Destruction Device

Device Trade Name: NiC1800 Needle Disposal System

Applicant's Name and Address:

NIC Limited
Box 4163
Honolulu, Hawaii 96812

Premarket Approval Application Number: P970036

Date of Approval SEP 26 1997

II. INDICATION FOR USE

The NiC1800 Needle Disposal System is a sharps needle destruction device that is intended for the disposal of standard plastic syringe-mounted hypodermic needles (19 gauge through 28 gauge, up to 2 inches in length) in patient treatment and clinical laboratory settings.

III. CONTRAINDICATIONS

The device is contraindicated for use in any potentially explosive environment or where flammable gases or fluids are stored or are in use e.g., operating room, emergency room, etc. Using this device near flammable materials may cause an explosion or fire that could result in significant injuries.

The device is contraindicated for use with syringes containing flammable liquids.

IV. WARNINGS AND PRECAUTIONS

The warnings and precautions can be found in the NiC1800's labeling.

V. DEVICE DESCRIPTION

The NiC1800 Needle Disposal System is a sharps needle destruction device that incinerates 19-28 gauge standard plastic syringe-mounted hypodermic needles using standard electrical current (110-120 volts). The device is composed of a base unit which houses the power supply, transformer indicator lights, a printed circuit board, and a disposable cartridge which contains the needle destruction apparatus and also acts as a closed and secure debris container. The cartridge slides on and off the base unit and has an average use life of 500 needle insertions. The NiC 1800 measures 11.4" x 5.1" wide x 4.3" high (290mm x 130mm x 110mm), and weighs 5.98 pounts (2,71 kg). The exterior surface is composed of flame retardant ABS plastic. The NiC1800 has rubber feet for stability on counter tops or flat surfaces. Needles are inserted vertically through an aperture in the top of the cartridge and guided to the electrode via an integrated diaphragm/guide system. Needles are destroyed by the delivery of an electric current across the width of the needle between two electrodes.

VI. ALTERNATIVE PRACTICES AND PROCEDURES

The disposal of standard syringe-mounted hypodermic needles in patient treatment and clinical laboratory settings is governed by the Occupational Safety and Health Act and the guidelines adopted by the institution. The method of needle disposal prescribed is the placement of the sharp in a sharps container.

VII. MARKETING HISTORY

Sales of the NiC1800 Needle Disposal System began in November 1996. As of July 30 1997, a total of 435 starter units (1 NiC1800 base unit and 1 C500 cartridge) and a total of 290 replacement cartridges have been sold in Mexico, the United Kingdom, and Malaysia.

VIII. POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH

There is no data to show that the use of this device with other types of needles, such as needles attached to metal syringes, suture, butterfly, or biopsy needles, or any other object is safe.

The NiC1800 does not have direct contact with the patient or the user when used as directed. Potential environmental effects have been assessed in the pre-clinical studies and have demonstrated the absence of any adverse environmental effects. No adverse effects were observed during the clinical studies.

IX. SUMMARY OF PRECLINICAL STUDIES

Test for Emission of Toxic Fumes and Particulates

The object of the test was to determine potential toxic fume emissions from the operation of the device. The sampling method was taken from the NIOSH Manual of Analytical Methods for the assessment of occupational exposure to determine the potential toxicants of concern in this protocol. During the destruction of 3 needles/minute for 120 consecutive minutes the levels of total particulates and specific metals were within the acceptable limits. The testing demonstrated that use of the device does not result in the generation of metal fumes of toxicological concern or particulate material, at levels that would represent a health concern to persons operating the device.

Generation of Heat

The object of the study was to determine the amount of heat generated during the use of the device that might represent a safety concern to the user. A series of temperature probes were placed at a variety of locations on the unit while it was exposed to intensive use. Measurements demonstrated that no significant heating of the base unit or cartridge occurs even after an extended period of continuous use. The maximum external temperature measured was within the ambient room temperature range and should not present a safety concern to personnel using the device.

Generation of Noise

The object of the study was to determine the noise level generated by the use of the device that may impact the Health Care Facility environment. Measurements were made of the sound level produced by the needle disposal device. Before tests were conducted, background noise levels in the test room were determined to be about 35dB(A). The sound level at one meter from the device when in use was found to range between 50-55dB(A), approximately the same noise level as generated by air conditioners in medical facilities.

Formation of Sparks

The potential for sparks has been addressed in the labeling under contraindication for use.

Failure to Completely Destroy the Needle

The device may require multiple insertions to completely destroy the needle. In both laboratory and clinical use studies, needles were satisfactorily destroyed after 1-3 insertions. In the event the needle is not completely destroyed, the user is directed to dispose of the remaining needle stub in a sharps container.

Stability

The device was tested for the force required to move or tip the device from the counter top position. The data did not indicate any instability of the unit under normal use.

Formation of Aerosols

The object of the study was to determine the potential for the formation of infectious aerosols generated from the use of the device. Both bacterial and viral contaminants were used to assess the potential for aerosolization of these substances during intense use of the device. The test was simulated for worse case using high titers of both organisms in a challenge fluid maintained at 37 ± 2 °C. Aerosolization was determined at the point of use rather than at user level. The device does not appear to be an aerosol generator because there were very few test organisms that grew on the culture plates. The labeling instructs the user to expel any fluids before using the device.

Simulated Use

The purpose of the study was to evaluate the efficacy of the needle destruction device to destroy needles. The definition of destroy for the purposes of this study is an operation applied to the needle that will result in a significant increase in the amount of force necessary for a needle stub to penetrate a thin polymeric barrier which closely represented skin. Efficacy was demonstrated using 2 production base units and two production C500 cartridges. Approximately 1000 needles were used in sizes ranging from 19-28 gauge and lengths up to 2 inches. The destroyed needles required an average penetration force of 4.9 kg. This was comparable to the average penetration force of a medium point ball point pen which was 4.9 kg. The data demonstrate that the force required for the destroyed needles to penetrate a polymeric barrier was greatly reduced.

Validating Cleaning

The purpose of the study was to validate the cleaning procedure. Two needle destruction devices were contaminated with British Soil and *Escherichia coli*. The device was cleaned with a 10% solution of bleach and allowed to sit for 10 minutes. The surface of the device was wiped with a clean soft cloth moistened with purified water. Test

organisms present after cleaning were extracted. A test was performed on the cloth to show that the cloth did not contain the test organisms. Cleaning results demonstrated a 5.7 Log reduction of organisms. The labeling contains the cleaning instructions derived from this study.

Electrical Safety Test

NiC Limited has commissioned an independent laboratory to evaluate the electrical safety of the NiC1800. Inchcape Testing Services tested the device according to UL3101-1, 1993, IEC61010-1 and found it to comply with the applicable requirements. The UL3101-1 and IEC1010 apply to Standard Electrical Equipment for Laboratory Use.

NiC limited also commissioned Intertek Testing Services to evaluate the Electro-Magnetic Compatibility. This testing service tested the device according to EN60601-1-2:1993 and found it to comply with the applicable requirements.

X. SUMMARY OF CLINICAL STUDIES

The objective of the clinical study was to demonstrate that the NiC1800 Needle Disposal System can safely and effectively be used in a representative health care setting to destroy standard syringe mounted plastic hypodermic needles in the range of 19 to 28 gauge and up to 2 inches in length. .

Study Design

The clinical study was a prospective study at 3 sites with an investigator and at least 2 operators at each site. The sites included a laboratory, physicians office, and a hospital clinic. Institutional Review Board approval was obtained for the study protocol as a non-significant risk device. The inclusion criteria consisted of 19 to 28 gauge needles that were up to 2 inches in length. Excluded from the study were butterfly needles, other specialty needles and needles attached to metal syringes. The pass criteria was destruction of the needle within 3 mm; the fail criteria was failure of the needle to destruct within 3 mm.

Reference needles were used by the operators at each site on 2 separate occasion. They were soiled prior to destruction using the simulated testing solution. The reference needles were collected by the study monitor and sent to an independent laboratory for evaluation. The simulated use was performed in order to supplement the range of needle sizes and types used at a given site.

Results: There were 1182 needles destroyed during the clinical study and 81 failures. This represents a 7% failure rate. During the study period, there were no observations of adverse events or needle sticks.

There were 81 incidences of failures of the needles to completely destruct which included the following:

- 61 partially incinerated needles were bent during the destruction process;
- 15 partially incinerated needles were greater than 3 mm after 3 insertions;
- 1 partially incinerated needle stuck in the cartridge (needle removed and disposed in sharps bin immediately);
- 2 failures due to a thermal trip; and,
- the cause of 2 failures was not recorded.

All failed needles were immediately disposed in sharps containers. The sponsor attributed the failures to operators not following the instructions for use. They were as follows:

30 needles that were used were outside the specified range;

a thermal trip occurred that was attributed to the operator exceeding the specification of the maximum insertion rate of 3 needles per minute in violation of the protocol and instructions for use; and,

a second thermal trip was attributed to the operator replacing the cartridge without waiting for the green light to stop flashing in violation of the protocol and instructions for use.

XI. CONCLUSIONS 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 an 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 NiC1800 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 SEP 26 1997

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

NiC1800 Needle Disposal System Operating Instructions

Text Only Version - For FDA Use

1.0 DEVICE DESCRIPTION

The NiCI800 Needle Disposal System is a table-top unit designed to destroy, through incineration, a full range of standard plastic syringe-mounted hypodermic needles in patient treatment and clinical laboratory settings using standard electrical current (110-120 volts). The needle destruction process takes place within seconds, in a closed disposable cartridge.

2.0 INDICATION FOR USE

The NiCI800 Needle Disposal System is a sharps needle destruction device that is intended for the disposal of standard plastic syringe-mounted hypodermic needles (19 gauge through 28 gauge up to 2" in length) in patient treatment and clinical laboratory settings.

3.0 CONTRAINDICATIONS

3.1 DO NOT use the NiCI800 Needle Disposal System in any potentially explosive environment, or where flammable gases or fluids are stored or are in use e.g., operating rooms, emergency room, etc.. Using this device near flammable materials may cause an explosion or fire that could result in significant injuries.

3.2 DO NOT use the NiCl8OO Needle Disposal System with syringes containing flammable liquid.

4.0 WARNINGS

4.1 The device should not be used to destroy any other needle types such as needles attached to metal syringes, sutures, butterfly, or biopsy needles or other objects because the safety and efficacy of using these objects in this device has not been established.

5.0 PRECAUTIONS

5.1 When operating this device follow universal safety precautions, including OSHA guidelines, when handling needles and other biohazardous materials.

5.2 DO NOT evacuate syringe contents into disposable cartridge. Allowing fluids or moisture into the cartridge could damage the unit or corrode electronics.

5.3 DO NOT destroy more than three needles per minute. Attempting to do so may result in overheating of the unit, which will cause the green light to flash.. Wait until solid green power light appears (5-10 minute wait) before resuming operation of unit.

5.4 Needle gauges higher than 26 G may need additional rotating and/or slight variation of insertion angle.

5.5 When a solid red warning light appears, do not attempt to insert needle into unit until the cartridge is replaced.

5.6 Do not touch needle stub after removal from unit because the stub may remain hot for a few seconds.

6. 0 SPECIFICATIONS

PHYSICAL DESCRIPTION

Weight:	5.98 lbs. (2.71 kg)
Dimensions:	11.4" x 5. 1 " x 4.3 " (290mm x 130mm x 1 10mm)
Power Supply:	110 - 120 volt AC
Current:	100VA
Noise:	Maximum 55 dB(A) intermittent
Fuses:	Two standard 5 amp fuses.

OPERATIONAL DESCRIPTION

Needle gauges: 19-28 gauge standard plastic syringe- mounted hypodermic needles.
Needle length: up to 2 inches
Operational capacity: maximum 3 needles per minute
Average cartridge use life: 500 insertions

Test data indicates cartridge use life will average 500 needle insertions (range of 436-585). The number of needles destroyed may be less than the number of insertions. Multiple insertions may be necessary to destroy a needle.

7.0 DIRECTIONS FOR USE

NOTE: TO AVOID INADVERTENT DAMAGE AND INJURY, IT IS IMPORTANT TO BE THOROUGHLY FAMILIAR WITH THESE INSTRUCTIONS BEFORE HANDLING THE DEVICE OR ITS COMPONENTS.

7.1 UNPACKING AND GENERAL INSTRUCTIONS

7.1.1 Thoroughly inspect the outside of all shipping containers for indications of damage. Contact the shipping firm as necessary to resolve shipping damage.

7.1.2 Carefully remove components from shipping cartons and packing material. Inspect all components carefully to make certain that they have not been damaged in shipment. If damaged, do not attempt to use the device, and contact your distributor with any questions or concerns.

7.1.3 The shipping carton should contain:

1 Base Unit.
1 C500 disposable cartridge and cap (stored under cartridge).
1 Power cord.
1 Operating Instructions.

7.1.4 Obtain a Return Goods Authorization Number from your distributor prior to returning any materials.

7.2 ASSEMBLY

Install the disposable cartridge by aligning on the base unit and pushing gently downward until the top surface of the disposable cartridge is flush with the top surface of the base unit.

Attach the power cord to the base unit. Plug the power cord into any standard 110-120 volt electrical outlet.

7.3 OPERATION

Failure to carefully follow all instructions may result in significant injury to the operator and damage the device.

DO NOT allow liquids or moisture into the disposable cartridge. Liquids could damage the unit or corrode the electronics.

PRECAUTION: WHEN OPERATING THIS DEVICE FOLLOW UNIVERSAL SAFETY PRECAUTIONS, INCLUDING OSHA GUIDELINES, WHEN HANDLING NEEDLES AND OTHER BIOHAZARDOUS MATERIALS.

7.3.1 Be sure the power switch is on, (1) position, (Fig. 3).

There are two indicator lights on the unit (green and red):

- Solid green light indicates unit is operational.
- Flashing green light indicates unit has overheated.
- Flashing red light indicates cartridge is nearing maximum number of insertions.
- Solid red light indicates unit is inoperable. Unit will remain inoperable until a new cartridge is attached. Dispose of cartridge as biohazardous waste.

7.3.2 With one hand grasp the syringe barrel firmly and insert the needle vertically into the opening on top of the disposable cartridge. (See Figure 4)

PRECAUTION: DO NOT EVACUATE SYRINGE CONTENTS INTO THE DISPOSABLE CARTRIDGE. ALLOWING FLUIDS OR MOISTURE INTO THE CARTRIDGE COULD DAMAGE THE UNIT OR CORRODE ELECTRONICS.

7.3.3 With one hand push the syringe downward until the needle cannot be inserted further. Make sure the entire needle has been fully inserted. An electrode cleaning mechanism will sound for approximately 7 seconds after the system is energized.

7.3.4 After the needle has been fully inserted into the cartridge, immediately rotate the syringe one quarter turn right then one quarter turn left. (See Figure 5)

7.3.5 Remove and visually inspect for proper incineration.

PRECAUTION: DO NOT TOUCH STUB AFTER REMOVAL FROM THE UNIT BECAUSE THE STUB MAY REMAIN HOT FOR SEVERAL SECONDS.

7.3.6 If needle is fully destroyed, (See Figure 6), dispose of syringe as a biohazardous waste.

7.3.7 If the needle is not completely destroyed, reinsert the remaining needle as described above, press down firmly, immediately rotate syringe one quarter turn right and one quarter turn left. Remove and visually inspect. Dispose of the syringe as a biohazardous waste.

7.3.8 If the needle is not completely destroyed after three insertions, dispose of syringe and remaining needle as a sharps biohazardous waste.

7.3.9 Needle gauges higher than 26G may require additional rotating and/or slight variation of insertion angle.

8.0 REPLACING A USED CARTRIDGE

Failure to carefully follow all instructions may result in significant injury to the operator and damage the device.

The Red Warning light begins to flash when cartridge is nearing maximum number of insertions. The Red Warning light remains on (no flashing) when maximum number of insertions is reached. The unit is inoperable when the red light remains on.

PRECAUTION: WHEN A SOLID RED WARNING LIGHT APPEARS, DO NOT ATTEMPT TO INSERT NEEDLE INTO UNIT UNTIL THE CARTRIDGE IS REPLACED.

8.1 Turn power to OFF (0) position and unplug the base unit before removing or installing a cartridge.

8.2 Remove cap from base of cartridge. Place the cap onto top of the disposable cartridge. Press down firmly until the cap locks into place.

NOTE: DO NOT CAP THE CARTRIDGE UNTIL THE CARTRIDGE IS TO BE DISPOSED. THE CAP CANNOT BE REMOVED ONCE IN PLACE (SEE FIGURE 7).

8.3 Slide the used disposable cartridge up and off the base unit. Dispose of all used cartridges as biohazardous waste and in accordance with internal healthcare procedures, and state and federal regulations. (See Figure 8)

8.4 Clean the outer surfaces of the base unit according to cleaning instructions (See Section 10.0).

8.5 Slide a new cartridge onto the base unit. Press gently downward until the top surface of the cartridge is flush with the top surface of the base unit.

8.6 Plug power cord into wall outlet and turn power switch to *ON* (1) position. The new disposable cartridge is now ready to destroy needles.

9.0 REPLACING FUSES

9.1 Turn power to OFF (0) position and unplug the base unit before removing or installing fuses.

9.2 Open the fuse drawer by sliding the release lever. (See Figure 2)

9.3 Remove fuse drawer and inspect fuses. If necessary, replace with standard 5 amp fuse(s), and slide the fuse drawer back into the base unit. Make sure the fuse drawer is fully inserted and the release lever is locked in place before turning power switch on.

10.0 STORAGE, CARE, AND CLEANING

The NiCI800 Needle Disposal System should be stored and maintained in the same manner as other precision medical devices used in patient treatment or laboratory settings. The system should not be exposed to extreme temperatures. The system should not be immersed in water or other cleaning solvents or fluids.

Turn the unit off and unplug before cleaning. Clean the NiCl8OO Needle Disposal System when the disposable cartridge is replaced or when the system has been soiled (base unit or cartridge). Wipe the outer surfaces of the base unit and disposable cartridge using a 10% bleach solution or similar commercially available disinfectant. Do not permit liquid to enter the disposable cartridge.

11.0 TROUBLE SHOOTING

PROBLEM: Unit will not operate.

Make sure the power cord is plugged into both the NiCl8OO Needle Disposal System and the electrical outlet.

Unit will not operate if solid red light is on. Replace cartridge. Make sure the power switch is in the ON (1) position.

Check fuses. Replace if necessary (See Figure 2). Use only standard 5 amp fuses.

PROBLEM: Needle not fully destroyed.

Follow Operating Instructions 7.3 - 7.3.9. With one hand reinsert syringe fully into unit, press down firmly, rotate one quarter turn right and one quarter turn left. If needle is not completely destroyed after three needle insertions dispose syringe and needle as sharps biohazardous waste.

PROBLEM: Green power light begins flashing.

This indicates unit has overheated. Dispose of unprocessed needle into a sharps biohazardous waste container. Wait until solid green power light resumes (average 5-10 minute wait) then use unit normally.

DO NOT DESTROY MORE THAN 3 NEEDLES PER MINUTE.

PROBLEM: Needle becomes stuck in unit.

DO NOT attempt to remove a needle that is stuck or lodged in the cartridge. Carefully remove cartridge and dispose as biohazardous waste. Insert new cartridge.

12.0 WARRANTY AND TECHNICAL / CUSTOMER SERVICE

If the NiCl8OO Needle Disposal System should become inoperable or dysfunctional as a consequence of manufacturer defect(s) in material or workmanship during a period of up to 1 year from the date of purchase, NIC Limited, at its sole option, will either repair or replace the device at no charge.

U.S. Distributor:

Name:

Address:

Telephone: