SUMMARY OF SAFETY AND EFFECTIVENESS DATA

I. GENERAL INFORMATION

Device Generic Name: Needle Destruction Device

Device Trade Name: Q-103 Needle Management Systems

Applicant's Name and Address:

QCare International, LLC.
680 Atlanta Country Club Drive
Marietta, Georgia 30067

Premarket Approval Application Number: P980020

Date of Approval: DEC 21 2000

II. INDICATION FOR USE

The Q-103 Needle Management System is a needle destruction device intended to be used in a home care environment to sever ½ inch hypodermic needles (gauges 28 – 29) attached to insulin syringes and store them until disposal.

III. DEVICE DESCRIPTION

The Q-103 Needle Management System is a hand held needle destruction device that operates from a battery pack consisting of four 1.2 volt AA Nickel Cadmium rechargeable batteries. It delivers 8 –12 amps of current that is sufficient to sever 28 – 29 gauge, ½ inch insulin needles. There is a mechanical overfill condition that prohibits rotation to the cut position. Inside the device is a storage area for the severed needles which has the capacity to hold 5,000 needles. The battery door and needle storage area have locking tabs to prevent opening.

The device weighs 6.5 ounces and measures 1 ½" x 3" x 5 ½". On the front of the unit is a red LED lamp that indicates when the battery needs recharging. The housing is constructed of chemical and flame retardant ABS plastic.

IV. CONTRAINDICATIONS

This device should not be used near flammable materials such as oxygen because it may cause explosions or fire that could result in significant injuries. Alcohol or other flammable liquids should not be used for cleaning or disinfecting the unit. Do not dispose of the device in recyclable waste containers.

V. WARNINGS AND PRECAUTIONS

The warnings and precautions can be found in the QCare Q-103 labeling.

VI. ALTERNATIVE PRACTICES AND PROCEDURES

The disposal of hypodermic needles is regulated by 29 CFR Part 1910.1030, "Bloodborne Pathogens" promulgated under the Occupational Safety and Health Act. The method of needle disposal prescribed is the placement of contaminated sharps in sharps containers.

VII. MARKETING HISTORY

The QCare Q-103 Needle Management System has not been marketed in the United States or in any foreign country.

VIII. POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH

There are no data to demonstrate the safe use of this device with needles, other than those indicated.

Potential adverse effects have been assessed in the design of the device. Pre-clinical and clinical studies have demonstrated the low potential of any adverse effects. No adverse effects were observed during the clinical studies.

IX. SUMMARY OF PRE-CLINICAL STUDIES

Test for Emission of Toxic Fumes

The purpose of the test was to identify and qualify airborne contaminants potentially generated during the operation of the Q-103 Needle Management System. Since the intended use of the device is to destroy needles, the test method was designed to analyze the components of the needles based on the potential to cause deleterious health effects. These components were determined to be chromium, nickel, manganese and iron. An airtight chamber with a sampling pump was constructed to collect air samples. There were 15 BD 10 cc syringes equipped with #304 needles destroyed during the air sampling. The samples were sent to the Wisconsin Occupational Health Laboratory, an American Industrial Hygiene Association accredited laboratory, for analysis. All samples were below detection limits for the indicated metals. The conclusion drawn was that no measurable concentrations of metals or their oxides are emitted from the Q-103 Needle Management System.

Generation of Heat

Since this is a hand held unit, the presence of heat would have been detected during the simulated use testing or the clinical study. No heating of the unit or syringe has been reported during use from the clinical study or the simulated use study. The generation of heat from the device should not present a safety concern to users.

Generation of Noise

The Q-103 Needle Management System has no parts that generate noise.

Formation of Sparks

Sparks are generated inside the device when needles are incinerated but are not emitted from the device. When the needle is not inserted into the device according to the directions for use, the sparks can be seen inside the device. The potential for sparks has been addressed in the labeling and under the Contraindications and Instructions for Use. The clinical study did not report any problems associated with sparks. The conclusion drawn from the clinical and pre-clinical studies is that the Q-103 should be contraindicated for use in any potentially explosive environment where flammable gases or liquids are used or stored. Alcohol or other flammable liquids should not be used for cleaning or disinfecting the device.

Stability

The Q-103 Needle Management System is a hand-held portable device.

Formation of Aerosols

The purpose of the test is to determine the potential for the formation of infectious aerosols generated from the use of the device. An SAS Air Sampler with TSA plates was set up inside a Class 100 workstation. The outside of the insulin syringe needles were contaminated with 10^5 suspension of Bacillus subtilis and blood. Ten contaminated syringes were destroyed. The plates were collected and incubated at 30-35°C for 24-48 hours. The positive control was an intact contaminated syringe needle and the negative control was sampled air, prior to destruction of the contaminated needles. No growth was detected on any of the plates except for the positive control. The device does not appear to be an aerosol generator.

Simulated Use

The purpose of the study was to determine whether the device can successfully destroy needles, the rate of destruction, and the battery performance. There were 2 studies conducted.

The purpose of the first study was to determine the rate of destruction and battery performance. It consisted of destroying 4452 (28 guage , ½ inch) needles contaminated with rabbit blood. Battery voltage and status of indicator light were recorded for each destruction.

Results: Of the 4452 needles destroyed, 26 were not successfully destroyed on the first try; 17 were subsequently destroyed on the second try. Seven of the remaining failures were due to the braided wire carrying the current from the battery circuit to the rotating head electrode being severed. To remedy this, the braided wire was increased to 18AWG. The reason for the last 2 failures was unknown. However, the unit successfully destroyed 2500 needles after the last failure.

The purpose of the second study was to determine the effectiveness of the device to destroy the needle. The cut, blunt end of the needle stub was tested to determine the increase in force necessary for the stub to penetrate a water filled surgical glove that closely resembled skin . The destroyed needle was attached to a force gauge device and the force required to penetrate the glove was measured. A force of 9 – 18 lbs of pressure was applied to the glove. The results

demonstrated that there were no punctures detected. The conclusion drawn from the study is that the Q-103 Needle Management System can effectively destroy insulin needles.

Validated Cleaning

Since this device is for home use, the cleaning directions with solutions that are compatible with the unit's material will be in the Instructions for Use.

Electrical Safety

The purpose of the test is to evaluate the electrical safety of the device. Intertek Testing Services evaluated the Q-103 Needle Management System. They found it to be compliant with the applicable requirements of UL2601-1, as well as CSA requirements for export to Canada.

The electromagnetic compatibility (EMC) testing was conducted by Intertek Testing Services, in accordance with the EN55011 Class B Group I standard for emissions and IEC 601-1 for immunity. Worst case conditions were used with the charger plugged into the unit. Ambient noise in the environment was 6 dB below applicable limits. Radiated emission testing found no measurable emissions above this level. The maximum line-conducted emissions were below standard limits by 12.4 dB. All appropriate EMC testing was completed and found to be compliant with EMC standards.

Leak Resistance

The purpose of the study was to determine whether any residuals liquid from the stored needles would leak. The device was filled with water and allowed to stand for 24 hours. No leakage was found.

Impact Resistance

The purpose of the study was to determine whether the device is capable of maintaining the stored contaminated needles when dropped. The device was dropped from a height of 1 meter. The glue seal on the battery door was cracked but the integrity of the container was not affected.

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Puncture Resistance

The purpose of the study was to determine if the Q-103 is able to maintain the destroyed sharps until disposal without the needles puncturing through the device. The test needles were placed in the Digital Force Gauge and the stage with the device was raised to meet the needle. The force was measured. The test criteria was either the needle punctures the device case or the needle bends under the force. A total of twelve needles was used in the test. All 12 needles collapsed and never penetrated the device.

The conclusion drawn from the leak resistance, impact resistance, and puncture resistance test data is that the Q-103 is capable of maintaining contaminated sharps until disposal.

X. SUMMARY OF CLINICAL STUDIES

The objective of the study was to demonstrate that the Q-103 Needle Management System can safely and effectively be used in a home care environment to sever ½ inch hypodermic needles (gauges 28 – 29) from insulin syringes and store them for disposal.

Study Design:

There were 16 diabetic subjects that participated in this study ranging in age from 21 – 83 years. Each subject was provided with the Q-103 for destruction of their insulin syringe needles for 30 days. During that time, the subjects were asked to fill out a daily questionnaire that would provide information on the use of the device. The study was deemed a non-significant risk and approved on December 15, 1997 by Western Institutional Review Board. There was one principal investigator. The inclusion criteria consisted of ½ inch, 28 – 29 gauge insulin syringe needles. The pass criteria was total needle destruction. Failure was defined as the failure of the needle to destruct after 2 attempts.

Results: The subjects reported a total of 1088 attempted needle destructions, ranging from 30 to 119 individually. The mean destruction rate was 96.7% with 1 subject at 77.5%. The subject with 77.5% rate, reported sparks, needle nub sticking and 16 unsuccessful needle destructions. Another subject's unit (no. 25) was replaced on day 20 of the study because its voltage detector's shut-off was set too high.

The failures were explained as follows:

The sparking seen by some of the subjects was due to the needle not having been inserted completely in the disposal orifice. The sparking is not emitted from the device; rather, the subject sees the sparking reflected inside the device because the needle and syringe is not inserted completely as instructed. When inserted correctly the sparking is not seen outside the device. To correct this problem, the firm has replaced the sides of the opening with a non-reflective surface. The unsuccessful needle destructions were due to the subject not following the instructions for use. If the needle is not inserted completely into the opening, the nub sticking and unsuccessful needle destructions may result.

Some subjects reported the indicator light was not on several times but, otherwise, the unit operated normally. This was explained as the voltage on the LED light was too high.

There were no adverse reactions reported.

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 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 Q-103 Needle Management System is safe and effective for its intended use.

The applicant's manufacturing facilities were inspected on MAY 15 2000 and found to be in compliance.

CDRH has determined that, based on the data submitted in the PMA, there is reasonable assurance that the Q-103 Needle Management System is safe and effective for its intended use. CDRH issued an approval order on

DEC 21 2000.

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.

XIV. REFERENCES

Guidance on the Content and Format of Premarket Approval Applications [PMA] for Sharps Needle Destruction Devices, Draft Document, Revised - March 4, 1999, and Guidance on the Content and Format of the Premarket Notification [510(k)] Submissions for Sharps Containers, October 1993.