K061933

Section 5

510(k) Summary

Submitted by:	Hager Worldwide, Inc. 13322 Byrd Drive Odessa, FL 33556
Prepared on:	October 25, 2006
Device name	The Hager MIRAMATIC Box Sharps Container The Cap Trap Needle Re-capper
Classification name	Sharps Container Accessory to Hypodermic Single Lumen Needle Re-capper Accessory to Hypodermic Single Lumen Needle
	The MIRAMATIC Box Sharps Container is classified as Class II, General Hospital Panel (80), Pro Code MMX. The device is codified at 21 C.F.R. § 880.5570.
	The Cap Trap Needle Re-capper is classified as Class II, General Hospital Panel (80), Pro Code FMI. The device is codified at 21 C.F.R. § 880.5570
Predicate Devices	Sage Sharps Disposal Containers with Screw top K980490; and HypoGrip™ (needle re-capper) K924820
Intended Use	The MIRAMATIC Box Sharps Container is intended for use in dental offices for collection and disposal of contaminated wastes and sharps. Indicated for use as an aid in minimizing needle stick injuries during needle disposal.
	The Cap Trap Needle Re-capper is intended for use in dental offices during uncapping/recapping procedures. Indicated for use as an aid in minimizing needle stick injuries during re-capping and needle disposal.
Technological Characteristics	The MIRAMATIC Box Sharps Container is designed for use with the MIRAMATIC cartridge syringe to enable single-handed disengagement, ejection and disposal of needles during dental procedures.
	The Cap Trap Needle Re-capper is a mechanical re-capper designed to allow single-handed re-sheathing so that the needle is re-sheathed without directing it toward any part of the body. It consists of a base, carrier plate and activation plate
Testing	Testing activities were conducted to establish the performance and reliability characteristics of the accessories. Testing included mechanical testing, cleaning and sterilization efficacy and simulated use evaluation.

NOV 16 2006

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Hager Worldwide, Incorporated
C/O Mr. James Delaney
Consultant to Hager
4 Lincoln Street
Andover, Massachusetts 01810

NOV 16 2006

Re: K061933
Trade/Device Name: Hager MIRAMATIC Box Sharps Container and Cap Trap Needle Re-Capper
Regulation Number: 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: October 25, 2006
Received: October 27, 2006

Dear Mr. Delaney:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

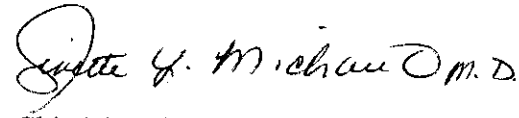
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4

Indications for Use Statement

Indications for Use

510(k) Number (if known): K061933

Device Name: Hagar MIRAMATIC Box Sharps Container

Indications for Use:

Intended for use in dental offices for collection and disposal of contaminated wastes and sharps.

Indicated for use as an aid in minimizing needle stick injuries during needle disposal.

For use with 25, 27 and 30 gauge long and short dental needles.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sheila N. Murphey

(Division Sign-Off)

Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

(Division Sign-Off) Number: K061933

Page __ of ___

(Posted November 13, 2003)

Indications for Use

510(k) Number (if known): K061933

Device Name: Cap Trap Needle Re-capper

Indications for Use:

Intended for use in dental offices during uncapping/recapping procedures.

Indicated for use as an aid in minimizing needle stick injuries during re-capping and needle disposal.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sign-Off)
...ion of Anesthesiology, General Hospital,
...ion Control, Dental Devices
Number K061933

Page __ of ___

(Posted November 13, 2003)