Section 5: 510 (k) Summary

Date of Preparation:

Device Names:	Sharp Chute ™ Model number(s): HS21001A – Red color material HS21001B – Yellow color material
Common Name:	Sharps Container
Classification Name:	Accessory to needles, hypodermic, single lumen, lancets
Regulation Number:	21 CFR 880.5570
Proposed Regulatory Class:	Class II
Device Product Code:	80 MMK
Medical Specialty:	General Hospital
Manufacturer:	Heathrow Scientific LLC. 620 Lakeview Parkway Vernon Hills, IL 60061
Official Contact Person:	Peter Hadjis Product Development Manager
Predicates:	Predicate devices to which Sharp Chute ™ is substantially equivalent: o K943139 – B-D, Guardian One Piece-Sharps Collectors o K990936 - Stik Stoppers, The Vault o K980490 - Sage Products, Sharps Containers with Screw Top Caps o K964387 - Graphic Controls, Point of use II Sharps-A-Gator

Device Description:

- The Sharp Chute ™ is a portable, 1.5 quart sharps container designed to be used in environments where larger containers are not desired. In addition, it is designed to fit into Heathrow Scientific's Droplet™ Blood Collection Tray.
- The Sharp Chute ™ is available in either translucent red or translucent yellow.
- Each component of the container assembly is made of injection molded polypropylene.

- The end user will be required to attach the dome assembly to the base by inserting the connection tabs into their corresponding slots.
- The Sharp Chute ™ is designed to withstand punctures by syringes, pen needles, and lancets.
- The Sharp Chute ™ is autoclavable and incineratable.
- The Sharp Chute ™ is NOT reusable.

Intended Use:

- The Sharp Chute ™ is an over-the-counter, single-use, disposable, non-sterile sharps container intended to be used with medical sharps including, but not limited to, hypodermic needles, syringes, lancets, and blood needles. The containers can be used in any area requiring sharps collection prior to their final disposal.
- When the container is filled to the max-capacity indicator, it is intended to be permanently locked and ultimately disposed of.

Technological Characteristics:

- Predicate devices and new device is made from same material; polypropylene.
- All predicate devices feature a close functions prior to permanent lock. The new device also has this feature. In addition to a close position, the new device also provides close icons on the outer dome to show the close position to avoid confusion from false locking.
- Predicate devices feature detailed labels with warning cautions. The new devices feature similar cautions with additional warnings for added safety.
- Predicate devices offer handle for transport. The new device offers a similar handle and has been tested to be able to support the full capacity of the unit.
- The new device has a unique rotating dome. Predicate units have screw top lids. Screw top lids and the new device rotating dome has lid on rail system as well to enclose device. Both methods of the screw top and rotating dome lid provide lock and close mechanisms during transport and engage in lock.
- The Sharp Chute™ has passed all tests against various standards by third party review. The third party involved in review was:

  Intertek
  4700 Broadmoor Ave SE, Suite 200
  Grand Rapids, MI 49512

Discussion:

The Sharp Chute™ has similar materials of construction and indications for fill and lock as the predicate devices. The new device has similar technological characteristics as compared to predicate devices for safety, function, and uses. There are safety precautions that both the predicate devices and the new device used to display cautionary warnings to users. These safety precautions are listed on unit labels and instructional sheets.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Heathrow Scientific, LLC
C/O Mr. Jay Y. Kogoma
Responsible Third Party Official
Intertek Testing Services
2307 East Aurora Road Unit B7
Twinsburg, Ohio 44087

JUL 28 2009

Re: K091690
Trade/Device Name: Sharp Chute™
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: MMK
Dated: July 13, 2009
Received: July 15, 2009

Dear Mr. Kogoma:

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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Anthony D. Watson for

Susan Runner, D.D.S., M.A.
Acting 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

510 (K) Number (if known):

Device Name: Sharp Chute ™
Model number(s): HS21001A – Red color material
HS21001B – Yellow color material

Indications For Use:

The Sharp Chute ™ is an over-the-counter, single-use, disposable, non-sterile sharps container intended to be used with medical sharps including, but not limited to, hypodermic needles, syringes, lancets, and blood needles. The containers can be used in any area requiring sharps collection prior to their final disposal.

When the container is filled to the max-capacity indicator, it is intended to be permanently locked and ultimately disposed of.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

ion Sign-Off)
n of Anesthesiology, General Hospital
Control, Dental Devices

nber: K091690