K063666

EXHIBIT #7

510K SUMMARY OF SAFETY AND EFFECTIVENESS
BIODEX SHARPS CONTAINER, MODEL #039-413

JAN 25 2007

The Biodex Sharps Container consists of an injection molded polypropylene container fitted with an injection-molded snap on cover with a connected lid to the cover. The lid snaps onto the cover when the container is filled. The cover and lid are shipped not installed on the container bottom so the containers can be nested to save space. The cover is snapped onto the cover before use. The cover has an oval opening into which the Sharps are dropped vertically into the container.

The Sharps Container is classified as a Class II accessory to a hypodermic needle (Section 880.5570): Classification Name: Container, Sharps 80 MMK.

The Biodex Sharps Container is substantially equivalent to the B-D Sharps Collector, Model #305469. Both containers have a cylindrical shape. Both are injection-molded polypropylene with snap on covers and lids. Both have a vertical entry for the sharps.

The Biodex Sharps Container fits into the locking lead-lined shield used in Nuclear Medicine Departments and clinics for contaminated sharps.

The Biodex Sharps Container labeling has the cautionary statement that,
"This container is puncture resistant, but not puncture proof. To avoid injury, examine the collector carefully before you fill, carry or dispose of it".

This container is labeled for single use only and has a label and marking for,
"Do not fill above this line".
The container also has an untextured section above the full line to help the user see that container is full.

The intended use of the vertical entry Sharps Container is to provide a receptacle for used, contaminated medical sharps and for enclosure during transport to ultimate disposal.

The container will be manufactured to the product specifications.

CERTIFICATION:
I hereby certify that this summary of Safety and Effectiveness applies for the above indicated device.

Date: 1/12/07

Name:

Clyde Schlein, Director of Regulatory Affairs & Compliance
Biodex Medical Systems
20 Ramsay Road
Shirley, New York 11967-4704
Phone: (631) 924-9000 ext. 2343

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Clyde Schlein
Director of Regulatory Affairs Compliance
Biodex Medical Systems, Incorporated
20 Ramsay Road
Shirley, New York 11967-4704

JAN 2 6 2007

Re: K063666
Trade/Device Name: Sharps Container
Regulation Number: 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: MMK
Dated: December 8, 2006
Received: December 11, 2006

Dear Mr. Schlein:

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

Indications for Use

510(k) Number (if known): K063666

Device Name: Sharps Container

Indications for Use: Our Vertical Entry Sharps Container provides a receptacle for used, contaminated medical Sharps and for enclosure during transport to ultimate disposal.

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)

Sheila P Murphy MD

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