DEC 17 2003

K032943 (pg 1 of 1)

stryker INSTRUMENTS

4100 East Milham Avenue
Kalamazoo, MI 49001
Phone (269) 323-7700
(800) 253-3210

510(k) Summary

Trade Name: Stryker Bone and Vertebral Body Biopsy Kit and Stryker Capture Bone and Vertebral Body Biopsy Kit

Common Name: Vertebral Bone Biopsy Needles

Classification Name: 876.1075 Gastroenterology-Urology Biopsy Instruments

Equivalent to: Parallax Clearview Plus Bone and Vertebral Biopsy Needles (K022169), Parallax Bone and Vertebral Body Biopsy Needles (K011206), IMS Mathis Vertebral and Bone Biopsy System (K990515)

Device Description: Stryker's Bone and Vertebral Body Biopsy Kits can be used as a biopsy tool to remove a sample of bone tissue from a vertebral body for diagnostic purposes using a coring, cutting or aspiration technique.

Stryker's Capture Vertebral Body and Bone Biopsy Kits can be used as a stand-alone biopsy tool to remove a sample of bone tissue from a vertebral body for diagnostic purposes using a coring, cutting or aspiration technique. The Stryker Capture Bone and Vertebral Body Biopsy Kit and Kit with Guidewire is used to remove a sample of bone tissue from a vertebral body for diagnostic purposes, as well as to provide and maintain access to the same surgical site.

Technological Comparison: Stryker's Bone and Vertebral Biopsy Kits are equivalent and operate similar to the predicate devices listed.

Submitted by: Dannielle C. Wheeler
Regulatory Affairs Representative, Stryker Instruments

9/19/2003

Signature Date

Date Submitted: 9/19/2003

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 17 2003

Ms. Danielle C. Wheeler
Regulatory Affairs Representative
Stryker Corporation
Stryker Instruments Division
4100 E. Milham Avenue
Kalamazoo, Michigan 49001

Re: K032943
Trade/Device Name: Stryker Bone and Vertebral Body Biopsy Kit and Stryker Capture Vertebral Body and Bone Biopsy Kit
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: II
Product Code: KNW
Dated: September 18, 2003
Received: September 23, 2003

Dear Ms. Wheeler:

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 (301) 594-4659. 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/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K032943

Device Name: Stryker Bone and Vertebral Body Biopsy Kit and Stryker Capture Vertebral Body and Bone Biopsy Kit

Indications For Use:

Stryker's Bone and Vertebral Body Biopsy Kits can be used as a biopsy tool to remove a sample of bone tissue from a vertebral body for diagnostic purposes using a coring, cutting or aspiration technique.

Stryker's Capture Vertebral Body and Bone Biopsy Kits can be used as a stand alone biopsy tool to remove a sample of bone tissue from a vertebral body for diagnostic purposes using a coring, cutting or aspiration technique. The Stryker Capture Bone and Vertebral Body Biopsy Kit and Kit with Guidewire is used to remove a sample of bone tissue from a vertebral body for diagnostic purposes, as well as to provide and maintain access to the same surgical site.

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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K032943