K040369

APR - 1 2004

510(k) Summary

Trade Name:	Stryker Consolidated Operating Room Equipment (CORE) System
Common Name:	Console
Classification Names:	Bone Cutting Instruments and Accessories. (per 21 CFR section 872.4120) Ear, Nose and Throat Electric or Pneumatic Surgical Drill. (per 21 CFR section 874.4250) Powered Simple Cranial Drill, Burrs, Trephines and their Accessories (per 21 CFR section 882.4310)
Equivalent to:	Stryker CORE Console (K032303), Stryker TPS Plus (K032117) Stryker TPS (Dental-K943540, ENT-K943569, Neuro-K943541), TPS Hermes (K991696), Stryker Navigation System (K012380) and Dyonics (K771218).
Device Description:	The device description of the Stryker System includes drills, shavers, shields, guards, motors, attachments, saws, wire drivers, collets, console, irrigation pump, cords, footswitch, handswitch, clips, tubing, cutting accessories, and sterilization cases. The scope of this modification is limited to the console of the system.
Intended Use:	The Stryker Consolidated Operating Room Equipment (CORE) System is intended for use in the cutting, drilling, reaming, decorticating, and smoothing of bone, bone cement, teeth and other related tissue in a variety of surgical procedures, including but not limited to Dental, ENT, Neuro and Endoscopic. It is also usable in the placement or cutting of screws, metal, wires, pins, and other fixation devices.
Technological Comparison:	Technological characteristics are the same as previously cleared for the Stryker CORE Console (K032303), Stryker TPS Plus (K032117), Stryker TPS System (K943540, K943569, K943541, and K991696), Stryker Navigation System (K012380) and Dyonics (K771218).
Submitted by:	Jean W. Sheppard Regulatory Analyst Stryker Instruments
Date Submitted:	February 5, 2004

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 1 2004

Stryker Instruments
Mr. Jean W. Sheppard
Regulatory Analyst
Instruments DIV
4100 East Milham Avenue
Kalamazoo, Michigan 49001

Re: K040369
Trade/Device Name: The Stryker Consolidated Operating Room Equipment (CORE) System
Regulation Number: 872.4120
Regulation Name: Bone Cutting Instrument and Accessories
Regulatory Class: II
Product Code: DZJ
Dated: February 5, 2004
Received: February 13, 2004

Dear Mr. Sheppard:

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) 594-5613. 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,

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 Statement

510(k) Number (K040369):

Device Name The Stryker Consolidated Operating Room Equipment (CORE) System

Indications The Stryker Consolidated Operating Room Equipment (CORE) System is intended for use in the cutting, drilling, reaming, decorticating, and smoothing of bone, bone cement and teeth in a variety of surgical procedures, including but not limited to Dental. It is also usable in the placement or cutting of screws, metal, wires, pins, and other fixation devices.

The Stryker Consolidated Operating Room Equipment (CORE) System **(K032303)** is also, intended for use in the cutting, drilling, reaming, decorticating, and smoothing of bone and bone cement in a variety of surgical procedures, including but not limited to Neuro and Endoscopic. It is also usable in the placement or cutting of screws, metal, wires, pins, and other fixation devices.

The Stryker Consolidated Operating Room Equipment (CORE) System **(K040300)** is also, intended for use in the cutting, drilling, reaming, decorticating, and smoothing of bone, bone cement and other bone related tissue in a variety of surgical procedures, including but not limited to ENT. It is also usable in the placement or cutting of screws, metal, wires, pins, and other fixation devices.

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

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

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