K040300

MAR - 3 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 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.
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:	February 19, 2004

TABLE 1-COMPARISON

ELEMENT OF COMPARISON	SUBJECT DEVICE: Stryker CORE ENT System Console	CLAIMED SE DEVICE # 1: TPS Plus System	CLAIMED SE DEVICE #2: Stryker CORE System Console	CLAIMED SE DEVICE #3: Stryker TPS Dental System	CLAIMED SE DEVICE #4: Stryker TPS Hermes System	CLAIMED SE DEVICE #5: Stryker Navigation System
510(k)	K040300	K032117	K0323003	K943540	K991696	K012380
Intended Use	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.	Intended for use in the cutting, drilling, reaming, decorticating, and smoothing of bone, teeth and other bone 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, wires, pins, and other fixation devices. It can also be used to cut metal.	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 Neuro and Endoscopic. It is also usable in the placement or cutting of screws, metal, wires, pins, and other fixation devices. The endoscopic applications with CORE include use with the SE5 Small Joint Shaver in the wrist for any need for morselization of tissue within the joint. Cutters w be used to debride synovitis, articular cartilag flaps, or torn ligaments when surgeons deem resection appropriate. Burs are indicated for management of osseous lesions such as eburnate articular surfaces or osteophytes.	Intended for use in the cutting, drilling, reaming, decorticating, and smoothing of bone, teeth and other bone related tissue in a variety of surgical procedures, including but not limited to Dental. It is also usable in the placement or cutting of screws, wires, pins, and other fixation devices.	Intended for use in the cutting, drilling, reaming, decorticating, and smoothing of bone, teeth and other bone related tissue in a variety of surgical procedures, including but not limited to Endoscopic. It is also usable in the placement of cutting of screws, wires, pins, and other fixation devices. It can also be used to cut metal. The endoscopic applications with TPS include use with the SE5 Small Joint Shaver in the wrist for any need for morselization of tissue within the joint. Cutters will be used to debride synovitis, articular cartilage flaps, or torn ligaments when surgeons deem resection appropriate. Burs are indicated for management of osseous lesions such as eburnated articular surfaces or osteophytes.	Intended for use as a planning and intraoperative guidance system to enable open or percutaneous image guided surgery. The system is indicated for any medical condition in which the use of image guided surgery may be appropriate and where a reference to a rigid anatomical structure such as the skull or vertebra can be identified relative to medical images.

Outer Profile	Bench-top style console with a liquid display screen and optional irrigation pump.	Bench-top style console with a liquid display screen and optional irrigation pump.	Bench-top style console with a liquid display screen and optional irrigation pump.	Bench-top style console with a liquid display screen and optional irrigation pump.	Bench-top style console with a liquid display screen and optional irrigation pump.	N/A
Handpiece Connector	Three connectors allow for three handpiece cords to be connected with two handpieces capable of running simultaneously.	Three connectors allow for three handpiece cords to be connected.	Three connectors allow for three handpiece cords to be connected with two handpieces capable of running simultaneously.	Three connectors allow for three handpiece cords to be connected.	Three connectors allow for three handpiece cords to be connected.	N/A
Footswitch Connector	Two connectors allow for two footswitches to run simultaneously	Yes	Two connectors allow for two footswitches to run simultaneously	Yes	Yes	N/A
Adjustable Operating Parameters	User used the LCD screen to set the desired operating parameters	User used the LCD screen to set the desired operating parameters	User used the LCD screen to set the desired operating parameters.	User used the LCD screen to set the desired operating parameters.	User used the LCD screen to set the desired operating parameters.	Speed Control on Handpiece
System Status Display	Displayed on LCD screen.	Displayed on LCD screen.	Displayed on LCD screen.	Displayed on LCD screen.	Displayed on LCD screen.	N/A
Software	Microprocessor	Microprocessor	Microprocessor	Microprocessor	Microprocessor	N/A
Non-volatile Memory	Yes- all current settings are stored when the power is down.	Yes- all current settings are stored when the power is down.	Yes- all current settings are stored when the power is down.	Yes- all current settings are stored when the power is down.	Yes- all current settings are stored when the power is down.	N/A
Power Source	Electricity	12Volt Supply	Electricity	12Volt Supply	Electricity	12Volt Battery Power Supply
Power Output	400 Watts	400 Watts	400 Watts	200 Watts	200 Watts	170 Watts
Wireless Tag Technology	Accessories are recognized and identified on the console screen	N/A	Accessories are recognized and identified on the console screen	N/A	N/A	N/A
Window Jog Capability	Window Jog allows the cutter to turn slowly which enables the user can stop the cutter in any position in the window.	Window Jog allows the cutter to turn slowly which enables the user can stop the cutter in any position in the window.	Window Jog allows the cutter to turn slowly which enables the user can stop the cutter in any position in the window.	N/A	N/A	N/A

Enhanced Serial Interface (IEEE1394 Firewire)	Serial communications channel between the console and other devices allowing the transfer of data and control information	N/A	Serial communications channel between the console and other devices allowing the transfer of data and control information	N/A	N/A	Instrument's position information passed to the host system through a standard serial link
Auxiliary Control	Mechanism to provide power and control to and retrieve data from handpiece mounted subsystems	N/A	Mechanism to provide power and control to and retrieve data from handpiece mounted subsystems	N/A	N/A	Wireless software control and active LED's are battery driven, but optional wire supplied power available.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 3 2004

Stryker Instruments
c/o Jean W. Sheppard
Regulatory Analyst
4100 East Milham Ave.
Kalamazoo, MI 49001

Re: K040300
Trade/Device Name: The Stryker Consolidated Operating Room Equipment (CORE) System
Regulation Number: 21 CFR 874.4250
Regulation Name: ENT electric or pneumatic surgical drill
Regulatory Class: Class II
Product Code: ERL
Dated: February 5, 2004
Received: February 9, 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) 594-4613. 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,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known):

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 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)

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K040300