K032117 1/1

AUG - 8 2003

510(k) Summary

Trade Name:	Stryker Total Performance (TPS) 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 TPS (Dental-K943540, ENT-K943569, Neuro- 943541), TPS Hermes (991696), 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 Total Performance (TPS) System is 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 of cutting of screws, wires, pins, and other fixation devices. It can also be used to cut metal.
Technological Comparison:	Technological characteristics are the same as previously cleared for the Stryker TPS System (K943540, K943569, K943541, and K991696), Stryker Navigation System (K012380) and Dyonics (K771218).
Submitted by:	Jean W. Sheppard Sr. Regulatory Affairs Representative Stryker Instruments
Date Submitted:	July 8, 2003

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 8 2003

Ms. Jean W. Sheppard
Senior Regulatory Affairs Representative
Stryker Instruments
4100 E. Milham Avenue
Kalamazoo, Michigan 49001

Re: K032117
Trade/Device Name: Stryker Total Performance System
Regulation Number: 21 CFR 872.4120, 874.4250, 882.4310, 882.6640
Regulation Name: Bone cutting instrument and accessories;
Ear, nose, and throat electric pneumatic surgical drill
Powered simple cranial drills, burrs, trephines, and their accessories
Dental operative unit and accessories
Regulatory Class: II
Product Code: DZI, ERL, HBE, EIA, HBC, HBE, HSZ, GEY
Dated: July 8, 2003
Received: July 9, 2003

Dear Ms. 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) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. 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 may be obtained 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 Statement

510(k) Number K032117

Device Name The Stryker Total Performance (TPS) System

Indications The Stryker Total Performance (TPS) System is 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 of cutting of screws, wires, pins, and other fixation devices. It can also be used to cut metal.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

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

510(k) Number K032117