SEP - 4 1997

stryker®
INSTRUMENTS
4100 East Milham Avenue
Kalamazoo, MI 49001
(616) 323-7700 (800) 253-3210

K972367

Device Name:

Classification Name:	Surgical Instrument Motors and Accessories/Attachments 21 CFR 878.4820, Class I
Common/Usual Name:	Battery Powered Surgical Instruments and Accessories
Proprietary Name:	Stryker System 4000

Device Sponsor:

Stryker Corporation
Instruments Division
4100 E. Milham Avenue
Kalamazoo, MI 49001
Registration No: 1811755

Regulatory Class: Class I

Summary of Safety and Effectiveness:

The Stryker System 4000 Battery Powered Heavy Duty Handpieces and Accessories are intended for use in cutting, drilling, reaming, decorticating, and smoothing of bone and other bone related tissue in a variety of surgical procedures. 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.

The Stryker System 4000 is comprised of drills, a reamer, a rotary driver, saws, rechargeable batteries, battery chargers, a battery protector kit, sterilization cases and racks, and cutting accessories. The system is designed to meet the IEC 601.1 safety standards.

The Stryker System 4000 handpieces, batteries, battery charger, battery protector kit, and other system accessories are equivalent in intended use, safety, and effectiveness to existing powered instrument systems and accessories being marketed by companies such as 3M, Zimmer, and Sodem. The Stryker sterilization cases, rack, and cutting accessories are equivalent in intended use, safety, and effectiveness to existing products being marketed by Stryker Pre- The1976 Medical Device Amendment.

The Stryker System 4000 Handpieces and Accessories do not raise any new safety and

effectiveness concerns when compared to similar devices already legally marketed. Therefore, the Stryker System 4000 Handpieces and Accessories are substantially equivalent to these existing devices mentioned above.

Melissa Harriger

Melissa Harriger
Regulatory Affairs Representative
Stryker Instruments

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 4 1997

Ms. Melissa Harriger
Regulatory Affairs Representative
Stryker® Instruments
4100 East Milham Avenue
Kalamazoo, Michigan 49001-6197

Re: K972367
Trade Name: Stryker System 4000 Heavy Duty Battery Powered Equipment
Regulatory Class: I
Product Code: KIJ
Dated: June 24, 1997
Received: June 25, 1997

Dear Ms. Harriger:

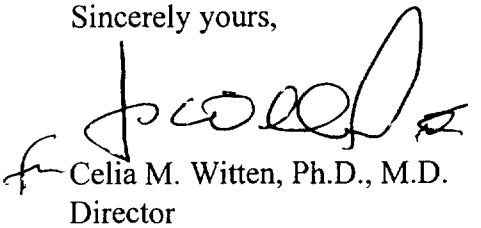
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



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

Enclosure

510(k) Number (if known): K972367

Device Name: Stryker System 4000 Heavy Duty Battery Power

Indications For Use:

The Stryker System 4000 Battery Powered Heavy Duty System is intended for use in the cutting, drilling, decorticating, and smoothing of bone and other bone related tissue in a variety of surgical procedures. 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.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDHR, Office of Device Evaluation (ODE)

(Division Sign-Off)
General Restorative Devices
510(k) Number K972367

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

(Optional Format 1-2-96)