K972069

stryker
INSTRUMENTS
4100 East Milham Avenue
Kalamazoo, MI 49001-6197
(616) 323-7700 (800) 253-3210

JUL 29 1997

**Device Name:**

| | |
|---|---|
| Classification Name: | Jet Lavage: 21CFR 880.5475, Class II |
| Common/Usual Name: | Pulsed Lavage |
| Proprietary Name: | Stryker InterPulse Lavage System |

**Device Sponsor:**

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

**Regulatory Class:** Class II

**Summary of Safety and Effectiveness:**

The Stryker InterPulse Lavage System is a pulsed lavage system intended for wound debridement, soft tissue debridement, and cleansing of the surgical or medical/clinical site.

The Stryker InterPulse System is a single patient use, sterile, disposable, pulsed lavage device. The system consists of an irrigation handpiece, irrigation tubing, irrigation tips, suction tips, suction tubing, and splash shields.

The Stryker InterPulse Handpiece is operated by batteries which are either located and sealed within the handpiece housing or in an external battery pack. The flow of irrigation is variable between approximately 100ml/min and 1500ml/min depending on which irrigation tip is attached to the handpiece as well as the amount of displacement of the handpiece trigger.

The InterPulse system includes an assortment of tips which provide a variation in irrigant flow rate and irrigation flow pattern. Tips that are indicated for wound and soft

tissue debridement do not exceed a pressure of 15 psi at the wound site. A Protective Plug allows the user to reuse the InterPulse handpiece on the same patient for subsequent hydrodebridement of chronic wounds. A lighted irrigation tip provides illumination of the irrigating site. This tip has a bulb that is illuminated by batteries located within the tip.

The Stryker InterPulse Lavage System is equivalent to existing marketed products by companies such as Davol and Davis+Geck. Power modality, intended use, and safety risks are all substantially equivalent.

The Stryker InterPulse System does not raise any new safety and efficacy concerns when compared to similar legally marketed devices.

Therefore, the Stryker InterPulse System is substantially equivalent to these existing devices.

Tammy Lounds
Associate Manager, Regulatory Affairs
Stryker Instruments

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Tammy Lounds
Associate Manager, Regulatory Affairs
Stryker® Instruments
4100 East Milham Avenue
Kalamazoo, Michigan 49001-6197

JUL 29 1997

Re: K972069
Trade Name: Stryker InterPulse System
Regulatory Class: II
Product Code: FQH
Dated: May 29, 1997
Received: June 3, 1997

Dear Ms. Lounds:

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): K972069

Device Name: InterPulse System

Indications For Use:

The Stryker InterPulse Lavage System is intended for wound debridement, soft tissue debridement, and cleansing of a medical, clinical, or surgical site. This includes cleansing of bone in surgical procedures, hydrodebridement of chronic wounds, debridement of loose skin on burn wounds, and cleansing wounds incurred from trauma.

(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 General Restorative Devices
510(k) Number K972069

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

(Optional Format 1-2-96)