

K972551

510(k) Summary

OCT 29 1997

Device: Artisan Pulse Lavage System

The Artisan Pulse Lavage System is intended to be used in the preparation of the intramedullary canal and/or bone surfaces in orthopedic procedures, including primary and/or revision total joint arthroplasty. This device may also be used to provide lavage for wound/burn irrigation/debridement in trauma situations, or any other situation where irrigation may be indicated. The pulsatile action of the pump helps to remove blood, tissue debris and foreign matter from the operative/wound site. When connected to a suction source the device can be used to aspirate material/fluids from the operative/wound site.

The Artisan Pulse Lavage System is a hand held pneumatic powered lavage system which utilizes a resterilizable handpiece, and sterile disposable pump cartridge with a choice of tubing configurations for intramedullary or soft tissue debridement. The system can also provide suction via the use of a pump cartridge with suction adapter. The system is connected to the power source by a resterilizable air hose.

The Artisan Pulse Lavage System is substantially equivalent to several other legally marketed devices. Examples of these are:

1. Exeter Lavage System - Howmedica (K790811)
2. Surgi-Lav 66 System - Stryker Corporation (Preamendment)
3. Pulsed Irrigation/Suction System - Stryker Corporation (K873466 and K951666)
4. Davol Simpulse Lavage System - Bard (K870915)
5. Davol Simpulse SOLO Pulsed Lavage System - Bard

For information contact: Margaret F. Crowe
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359 Veterans Boulevard
Rutherford, NJ 07070
(201) 507-7431
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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Margaret F. Crowe
Manager, Regulatory Affairs
Howmedica Incorporated
359 Veterans Boulevard
Rutherford, New Jersey 07070

OCT 29 1997

Re: K972551
Trade Name: Artisan Pulse Lavage System
Regulatory Class: II
Product Code: FQH
Dated: October 6, 1997
Received: October 7, 1997

Dear Ms. Crowe:

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.

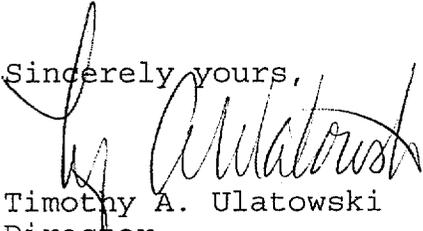
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, 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) 594-4618. 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,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

, Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Artisan Pulse Lavage System

Indications for Use:

The Artisan Pulse Lavage System is intended to be used in the preparation of the intramedullary canal and/or bone surfaces in orthopedic procedures, including primary and/or revision total joint arthroplasty. This device may also be used to provide lavage for wound/burn irrigation/debridement in trauma situations, or any other situation where irrigation may be indicated. The pulsatile action of the pump helps to remove blood, tissue debris and foreign matter from the operative/wound site. When connected to a suction source the device can be used to aspirate material/fluids from the operative/wound site.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) *Fabiana Cruz*
Division of Dental, Infection Control,
and General Hospital Devices

1972551

Prescription Use _____ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Prescription Use _____
(Per 21 CFR 801.109)