

K970916

510(k) Summary

JUN 20 1997

Global Medical Products, Inc. d/b/a Tava Surgical Instruments
1725 S. Rainbow Blvd., Suite 25
Las Vegas, Nevada 89102
Telephone: 702-228-1193; Fax: 702-228-1197

Contact Person: Tonya Balaban, Quality Assurance/Regulatory Affairs

Trade Name: Tava Surgical Instruments L31 H.V. Pulse Lavage
Common Name: Pulse Lavage
Classification Name: Lavage, Jet

Tava Surgical Instruments' L31 H.V. Pulse Lavage is substantially equivalent to like devices in commercial distribution. The Tava L31 Pulse Lavage utilizes the same pump set as its predecessor, the L20 Pulse Lavage, with a similar drive mechanism of the MicroAire® Hi Speed Pulse Lavage 4740.

Tava Surgical Instruments' L31 H.V. Pulse Lavage is an ergonomically designed pneumatic instrument. The hatch of the cradle is raised in order to insert single-use sterile pump sets which isolates the sterile fluids from the instrument. Activation of the instrument causes engagement of the pump set and pulsates the sterile fluids into the surgical site to remove blood and debris.

The L31 H.V. Pulse Lavage is utilized in trauma cases, hip and knee replacement surgery and other soft tissue procedures. The pulsation of sterile fluids into the surgical site facilitates removal of blood and debris by moving it to the surface.

Similar to the MicroAire® Hi Speed Pulse Lavage 4740, the instrument is powered by compressed, dry air or nitrogen. Activation of the instrument is accomplished by depressing the lever located in the handle of the instrument. Air flow into the instrument causes the rotary motor to drive the pulsating action of the pump.

Pulse Lavage systems currently on the market are used in conjunction with a pump set in order to achieve the necessary pulsation of the sterile fluids. The L31 H.V. Pulse Lavage engages the single-use pump set in a pumping action to introduce sterile fluids to the surgical sight in a pulsating action. The pulsation of the sterile fluids brings debridement to the surface and removes it from the surgical site.

The L31 H.V. Pulse Lavage and similar devices have components that are of similar materials that are well known and extensively used by medical device manufacturers. In addition, the Tava Surgical Instruments L31 H.V. Pulse Lavage utilizes current and recognized technology. Therefore, the L31 H.V. Pulse Lavage is as safe and effective as it equivalent the MicroAire® Hi Speed Pulse Lavage 4740 and does not raise additional questions concerning safety and effectiveness.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 20 1997

Ms. Tonya Balaban
Quality Assurance/Regulatory Affairs
Global Medical Products, Incorporated
1725 South Rainbow Boulevard, #25
Las Vegas, Nevada 89102

Re: K970916
Trade Name: H.V. Pulse Lavage (L31 Series)
Regulatory Class: II
Product Code: FQH
Dated: April 7, 1997
Received: April 11, 1997

Dear Ms. Balaban:

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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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.

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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 at (301) 443-6597.

Sincerely yours,



for 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 of the Tava Surgical Instruments
L31 Series H.V. Pulse Lavage**

Tava Surgical Instruments' L31 Series H.V. Pulse Lavage is intended to be utilized in the debridement of the surgical site during trauma cases, hip and knee arthroplasty cases and soft tissue surgery.