



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JUL 25 1997

Ms. Diana Preston  
Regulatory Affairs Specialist  
Walter Lorenz Surgical, Incorporated  
1520 Tradeport Drive  
Jacksonville, Florida 32218

Re: K972074  
Trade Name: Suction Instrumentation  
Regulatory Class: II  
Product Code: GCX  
Dated: July 11, 1997  
Received: July 14, 1997

Dear Ms. Preston:

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

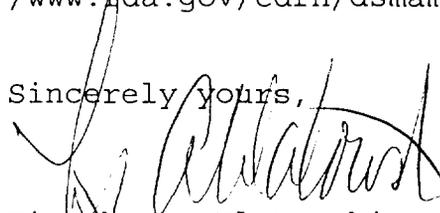
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through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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

JUL 25 1997

**SUMMARY OF SAFETY AND EFFECTIVENESS****Proprietary Name:** Suction Instrumentation**Classification Name:** Vacuum-Powered Body Fluid Suction Apparatus**Device Classification:** Class II**Device Product Code:** 80GCX (CFR 880.6740)**Intended Use:** The suction devices, when attached to an external source of vacuum, are used for aspiration, removal, or sampling of body fluids during surgical procedures.**Device Description:** These devices are rigid, hollow tips or tubes, that when attached to an external source of vacuum are used for aspiration, removal, or sampling of body fluids during surgical procedures. Some suction devices are fitted with Fiber Optic bundles.**Sterility Information:** Devices are provided non-sterile.**Substantial Equivalence:** The suction devices marketed by competitors displayed in Attachment III are believed to be substantially equivalent to Lorenz Suction Tips and Tubes based on;

- The intended uses for devices are equivalent
- The devices have the same technological features
- The safety and effectiveness of the devices are equivalent

**Potential Risks:**

- Improper selection of tips and tubes can impair the proper function of the system
- Occlusion of passageways can result in inadequate suction.

K972074

510(k) Number (if known): unknown

Device Name: Lorenz Suction Tips and Tubes

Indications For Use: The suction devices, when attached to an external source of vacuum, are used for aspiration, removal, or sampling of body fluids during surgical procedures.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) *Patricia Cucente*  
Division of Dental, Infection Control,  
and General Hospital Devices  
510(k) Number K972074

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-The-Counter Use   
(Optional Format 1-2-96)