3/30/99

510(k) Summary
for
SAPHLIFT

K990062

1. SPONSOR

Genzyme Surgical Products
5175 South Royal Atlanta Drive
Tucker, GA 30084

Contact Person: Michelle Johnston
Telephone: 770-934-8659

Date Prepared: January 7, 1999

2. DEVICE NAME

Proprietary Name: SAPHLIFT
Common/Usual Name: Surgical instrument holder
Classification Name: Manual Surgical Instrument

3. PREDICATE DEVICES

Leonard Arms (K951854)
Kronner Low Profile Scope Holder (K973543)

4. INTENDED USE

The SAPHLIFT is a holding and manipulating arm for use in surgery which allows the operating team to hold surgical instruments in a given position and to change that position immediately with one hand.

5. DEVICE DESCRIPTION

The SAPHLIFT consists of three main components: an articulated arm that clamps to the rail of the surgical bed, an instrument holder, and a compressed gas supply to maintain the pneumatic pressure to hold the instrument in place. Ball joints in the articulated arm and instrument holder allow for a wide variety of instrument

positions. Repositioning of the instrument is by means of a control lever that releases the pneumatic pressure when pressed and locks the instrument in place when released. The SAPHLIFT is reusable and is sterilized by steam autoclave.

6. BASIS FOR SUBSTANTIAL EQUIVALENCE

The SAPHLIFT has the same intended use for holding and positioning instruments during surgery, and is substantially equivalent, in terms of technological characteristics, as compared to the predicate devices. The SAPHLIFT and the Kronner devices both have articulated arms that are adjustable by means of ball joints. The Kronner device also incorporates articulated hinges. The Leonard Arms differs slightly in that the instrument is moved by way of a telescoping arm. The SAPHLIFT and Kronner devices both use positive pressure to hold the instrument in place, while the Leonard Arms uses a vacuum. All three devices are reusable after cleaning and sterilization.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 30 1999

Ms. Ruth Forstadt
Associate Consultant
Genzyme Surgical Products
c/o Medical Device Consultants, Inc.
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K990062
Trade Name: SAPHLIFT
Regulatory Class: II
Product Code: MDW and GCJ
Dated: January 7, 1999
Received: January 8, 1999

Dear Ms. Forstadt:

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 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) 594-4595. 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): K990062

Device Name: SAPHLIFT

Indications For Use:

The SAPHLIFT is a holding and manipulating arm for use in surgery which allows the operating team to hold manual surgical instruments and the SaphLite Retractor in a given position and to change that position immediately with one hand.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K990062

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

(Optional Format 1-2-96)