K974164

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510(k) Summary

DEC 18 1997

ELECTRO MEDICAL SYSTEMS SA
LITHOCLAST® MASTER Handpiece
and
3.2 mm Probe

1. Sponsor

ELECTRO MEDICAL SYSTEMS SA
Chemin de la Vaurpilliere 31
CH-1260 Nyon
Switzerland

Contact Person: Manfred Schulz
General Manager

Date Prepared: October 31, 1997

2. Device Name

Trade/Proprietary Name:	LITHOCLAST® MASTER Handpiece and 3.2 mm Probe
Common/Usual Name:	Accessories to endoscopic intracorporeal pneumatic lithotripter
Classification Name:	Accessories to electrohydraulic lithotripter (Class III)

3. Intended Use

The LITHOCLAST® MASTER Handpiece and the 3.2 mm probe have the same intended use as their predicate accessories, that is, for the fragmentation of urinary tract calculi, including renal, ureteral and bladder stones, through rigid or semirigid endoscopes. The 3.2 mm probe is specifically indicated for use in fragmenting large stones in the bladder and kidney.

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4. Device Description

MASTER Handpiece

The MASTER Handpiece is 18 mm in diameter, 228 mm long, and is constructed of aluminum alloy. The proximal end of the handpiece is connected to the LITHOCLAST pressure regulator. The chosen treatment probe is attached to the distal end of the handpiece using a screw cap. The metal projectile inside the handpiece is driven forward by the pressure from the pressure regulator. The energy from the projectile is transmitted to the probe by a shock transmitter at the distal end of the handpiece. The handpiece is sealed at both the distal and proximal ends, which: (1) prolongs the life time of the handpiece by preventing dirt, moisture and other particles from entering the handpiece; and (2) allows for the changing of probes during a treatment without the risk of breaking sterility.

3.2 mm Probe

The 3.2 mm probe is a rigid Type 304 surgical grade stainless steel rod that acts to couple the shockwave from the handpiece to the target stone. The probe is reusable and may be sterilized by steam sterilization according to standard hospital procedures.

5. Basis For Substantial Equivalence

MASTER Handpiece

The MASTER Handpiece is substantially equivalent to the EMS Standard Handpiece that was cleared for marketing under K951531 and K963285. The main difference between the two devices is that the MASTER Handpiece is sealed at both the distal and proximal ends, while the Standard Handpiece is open and requires the use of a silicone sleeve to provide a watertight seal between the probe and the handpiece. Life time and probe displacement tests were performed to support the substantial equivalence of the MASTER Handpiece.

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3.2 mm Probe

The EMS 3.2 mm probe is substantially equivalent to the EMS probes with smaller diameters (0.8, 1.0, 1.6, 2.0 mm). These predicate devices were cleared for marketing under K951531 and K963285. The main difference between these devices is the probe diameter. The larger 3.2 mm probe is specifically intended for use in fragmenting large stones in the bladder and kidney. Probe velocity and displacement tests, impact pressure, disintegration efficiency, and in-vitro tissue impact studies were performed to support the substantial equivalence of the 3.2 mm probe.

DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 18 1997

ELECTRO MEDICAL SYSTEMS SA
c/o Ms. Rosina Robinson
Senior Staff Consultant
Medical Device Consultants, Inc.
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K974164
EMS Swiss LITHOCLAST® MASTER Handpiece and 3.2mm Probe
Dated: October 31, 1997
Received: November 5, 1997
Regulatory class: III
21 CFR §876.4480/Product code: 78 FFK

Dear Ms. Robinson:

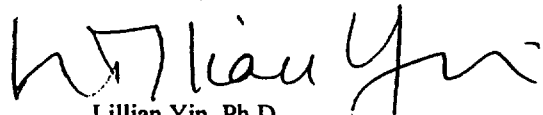
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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) 594-4613. 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,



Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K974164

Device Name: SWISS LITHOCLAST® MASTER HANDPIECE and 3.2 MM PROBE

Indications For Use:

The SWISS LITHOCLAST® MASTER HANDPIECE and the 3.2 MM PROBE are intended to be used as accessories to the EMS Swiss LITHOCLAST® Lithotripter for the fragmentation of urinary tract calculi, including renal, ureteral and bladder stones, through rigid or semirigid endoscopes. The 3.2 mm Probe is specifically indicated for use in fragmenting large stones in the bladder and kidney.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert P. Gatling
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K974164

Prescription Use ✓ OR Over-the-Counter Use ___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)