JUL 27 1999

K992251

510(k) Summary
for
ELECTRO MEDICAL SYSTEMS SA
SWISS LITHOCLAST® MULTIPURPOSE PROBE

1. SPONSOR

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

Contact Person: Giani Campana
Quality Manager

Date Prepared: June 30, 1999

2. DEVICE NAME

Trade/Proprietary Name:	Swiss LITHOCLAST® Multipurpose Probe
Common/Usual Name:	Accessory to endoscopic intracorporeal pneumatic lithotripter
Classification Name:	Accessory to electrohydraulic lithotripter (Class III)

3. INTENDED USE

The Swiss LITHOCLAST® Multipurpose Probe is intended to be used as an accessory to the EMS Swiss LITHOCLAST® Lithotripter for the fragmentation of ureteral calculi through rigid or semi-rigid endoscopes.

4. DEVICE DESCRIPTION

Swiss LITHOCLAST® Multipurpose Probe

The Multipurpose Probe is a rigid, 3 Fr (1.0 mm) Type 304 surgical grade stainless steel rod that acts to couple the shockwave from the handpiece of the target to the stone. A lateral notch in the distal end of the probe allows for fixation of mobile ureteral stones, thus reducing the risk of stone push back in the ureter. The probe can be reused five times and may be sterilized by steam sterilization according to standard hospital procedures.

5. BASIS FOR SUBSTANTIAL EQUIVALENCE

The Multipurpose Probe is substantially equivalent to the EMS 1.0 mm Probe. This predicate device was cleared for use in fragmenting ureteral and bladder stones under K951531 and renal stones under K963285. The main difference between these devices is the distal, lateral notch of the Multipurpose Probe which serves for tangential fixation of mobile stones. The Multipurpose Probe is specifically intended for use in fragmenting of stones in the ureter.

Probe longevity testing, probe tip velocity and displacement testing, and clinical use assessment were performed to support the substantial equivalence of the Multipurpose Probe to the 1.0 mm LITHOCLAST ® Probe.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Electro Medical Systems SA
c/o Ms. Sheila M. Hemeon-Heyer, Esq., RAC
Senior Staff Consultant
Medical Device Consultants, Inc.
49 Plain Street
North Attleboro, MA 02760

Re: K992251
Swiss LITHOCLAST® Multipurpose Probe
Dated: July 2, 1999
Received: July 6, 1999
Regulatory Class: III
21 CFR §876.4480/Procode: 78 FFK

Dear Ms. Hemeon-Heyer:

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 legally marketed predicate 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 requirements, 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/dsma/dsmamain.html".

Sincerely yours,

CAPT Daniel G. Schultz, M.D.
Acting 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): K992251

Device Name: SWISS LITHOCLAST® MULTIPURPOSE PROBE

Indications For Use:

The Swiss LITHOCLAST® Multipurpose Probe is intended to be used as an accessory to the EMS Swiss LITHOCLAST® Lithotripter for the fragmentation of ureteral calculi through rigid or semi-rigid endoscopes.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K992251

(Optional Format 1-2-96)