K011873

AUG 31 2001

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
Dornier Medical Systems, Inc.'s *Compact Alpha* Lithotripter

In response to the Safe Medical Devices Act of 1990, the following is a summary of the safety and effectiveness information upon which the substantial equivalence determination is based.

The safety and effectiveness of the Dornier *Lithotripter S* with the EMSE 220f as well as the Dornier *Lithotripter S-XP* with EMSE 220F-P is based upon a determination of the substantial equivalence as well as the safety and effectiveness of its predicate devices, which includes the following: Dornier MFL5000 (P840008 / S24/S40/S45), Dornier *Lithotripter S* (P840008 / S64) and Siemens Lithostar C (P870018 / S11).

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Dornier Medical Systems, Inc.
1155 Roberts Boulevard
Kennesaw, GA 30144

Phone: 770-426-1315
Facsimile: 770-514-6288
Date Prepared: June 14, 2001

Contact Person: Suzanne Courtney

Phone: 770-514-6204
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Name of Device and Name/Address of Sponsor

Dornier *Lithotripter S* & Dornier *Lithotripter S-XP*
Dornier Medical Systems, Inc.
1155 Roberts Boulevard
Kennesaw, GA 30144

Classification Name

According to 21 CFR § 876.5990, FDA has classified extracorporeal shock wave lithotripters as Class II device with special controls. The Product Code for these lithotripters is 78 LNS..

Predicate Devices

Dornier MFL5000 (P840008 / S24/S40/S45)
Dornier *Lithotripter S* (P840008 / S64)
Siemens Lithostar C (P870018 / S11)

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Intended Use

The Dornier *Compact Alpha* Lithotripter is indicated for fragmentation of 5-25 mm kidney stones such as renal calyx stones and renal pelvic stones and for upper, middle and lower ureteral stones $\geq$ 4mm.

Technological Characteristics and Substantial Equivalence

From a clinical perspective and comparing design specifications, the Dornier *Lithotripter S* with the EMSE 220f as well as the Dornier *Lithotripter S-XP* with EMSE 220F-P, and the predicate devices are substantially equivalent and have the same intended use. Based on the technological characteristics and overall performance of the devices, Dornier Medical Systems, Inc. believes that no significant differences exist between the Dornier *Lithotripter S* with the EMSE 220f as well as the Dornier *Lithotripter S-XP* with EMSE 220F-P and the predicate devices, Dornier MFL5000 (P840008 / S24/S40/S45), Dornier *Lithotripter S* (P840008 / S64) and Siemens Lithostar C (P870018 / S11).

Dornier Medical Systems, Inc. believes the minor differences of the Dornier *Lithotripter S* with the EMSE 220f as well as the Dornier *Lithotripter S-XP* and its predicate devices should not raise any concerns regarding the overall safety or effectiveness.

Advisory: This information was prepared for the sole purpose of compliance with the Safe Medical Devices Act of 1990. It does not imply that the procedures described herein can be performed with the equipment described without substantial risk of personal injury or death to patients due to operator error or in procedures requiring a high degree of skill.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 31 2001

Ms. Suzanne Courtney
Manager, Regulatory and Quality Affairs
Dornier Medical Systems, Inc.
1155 Roberts Blvd.
KENNESAW GA 30144

Re: K011873
Dornier Lithotripter Doli S and Doli S-XP
Dated: August 7, 2001
Received: August 8, 2001
Regulatory Class: II
21 CFR §876.5990/Procode: 78 LNS

Dear Ms. Courtney:

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), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4,xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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, International and Consumer 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,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

PREMARKET NOTIFICATION

INDICATIONS FOR USE STATEMENT

510(k) Number: K011873

Device Name: Dorner *Lithotripter S* ("*DoLi S*") & Dornier *Lithotripter S-XP* ("*DoLi S-XP*")

Indications for Use:

Indicated for the fragmentation of 5-25 mm kidney stones such as renal calyx stones and renal pelvic stones and for upper, middle and lower ureteral stones ≥ 4mm.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ or Over-the-Counter Use _____

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K011873