PHX Technologies Corporation

Post Office Box 1059, Lewisville, Texas 75067 (817)387-5696 FAX (817)382-0577

K971123

510(K) Summary

JUN 27 1997

Date: 21 March 1997

Trade Name: Stone Extractor

Common Name: Stone Extractor

Classification Name: Unknown

Device Description: The stone extractor has a nominal diameter of 0.392", a tube length of 13.0" and has a scoop 0.6" long. The surface of the stone extractor is polished on the proximal 3.0" and matte finished on the remaining 10.0". The stone extractor is fabricated from 304 stainless steel.

Intended Use: This stone extractor is indicated for use in laproscopic surgery for the removal of gall stones.

Substantial Equivalence: This stone extractor, Submitted Device is, substantially equivalent to the stone extractor, Predicate Device, currently being sold in the United States by American Hydro-Surgical Instruments, Inc., 430 Commerce Drive, Delray, Florida 33445 To the best of our knowledge, this predicate devices is being "legally" marketed.

Comparison to Predicate Device:

Attribute	Predicate Device	Submitted Device
Material of construction,Stone extractor	Stainless steel	Stainless steel
laterial of construction, handle	Aluminum	Stainless steel
Stone extractor, nominal diameter, inches	0.392"	0.392
Stone extractor, nominal length, inches	13.0"	13.0"
Stone extractor, nominal length, Scoop,inches	0.6"	0.6"
Reuseability	Reuseable	Reuseable
Sterility	Sold non-sterile	Sold non-sterile

Submitter's Name	PHX Technologies Corporation
Submitter's Address:	1032 Shady Oaks Drive, No. 100, Denton, TX 76205
Submitter's Phone #:	(817) 387-5696
Submitter's FAX:	(817) 382-0577
Submitter's Contact Person:	James F. Chapel

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 27 1997

Mr. James F. Chapel
President
PHX Technologies Corporation
P.O. Box 1059
Lewisville, Texas 75067

Re: K971123
Stone Extractor
Dated: May 13, 1997
Received: May 19, 1997
Regulatory class: II
21 CFR §876.1500/Product code: 78 KOG

Dear Mr. Chapel:

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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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) 594-4616. 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): K971123

Device Name: Billiary Stone Extractor

Indications For Use:

Indications: This instrument is indicated for use with a compatible trumpet valve during endoscopic surgery for facilitating the removal of gallstones.

Contraindications: This instrument is contraindicated for use when, in the judgment of the physician, it's use would be contrary to the best interest of the patient.

Precautions: During surgery this instrument must be handled with care to avoid misuse and possible damage. Use care when passing this instrument through a cannula. When inserting the instrument into a cannula that has a hinged valve, make sure that the valve is fully open. When removing the instrument from a cannula that has a hinged valve, make sure that the valve is fully open and pull the instrument straight out, as lateral or side movement may cause the tip to hang on the valve.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K971123

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

(Optional Format 1-2-96)