SOHNIKS ENDOSCOPY, Inc.

930 Blue Gentian Road
Suite 1400
Eagan, MN 55121
(651) 452-4059
Fax (651) 452-4056

FEB 0 7 2003

K023783

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Device act of 1990 and 21 CFR 807.92. All data in this document is accurate and complete to the best of Söhniks Endoscopy's knowledge.

Applicant: Söhniks Endoscopy, Inc.
930 Blue Gentian Road
Suite 1400
Eagan, MN 55121
651-452-4059 phone
651-452-4056 fax

Contact: Marc Hoskins

Device ID: Arthroscope

Indication: The Söhniks Endoscopy Arthroscopes are intended for use by qualified surgeons during procedures of small and large joints. The intended use for Söhniks Endoscopy, Inc.'s arthroscopes are for examining, diagnosing, visualizing and to aid in treating the interior problems of orthopedic joints, otolaryngology, rhinology, endoscopic plastic and reconstructive surgery. Our arthroscopes are intended for use in the shoulder, wrist, knee, ankle, elbow, and jaw and visualization of the hip joint to diagnose disease and removal of loose bodies.

Device Description: The Söhniks Arthroscopes are reusable manually operated surgical devices that are provided in 0, 30, 45, and 70 degree direction of view. The Arthroscopes are provide non-sterile and must be cleaned and sterilized by the user prior to each use. The components that contact the body are composed of surgical grade stainless steel, which is commonly used in medical devices and has a long history of biocompatibility for human use.

Substantial Equivalence: The Söhniks Arthroscope is substantially equivalent to its predicate devices. The basic design, materials and intended uses are the same and there are no new issues of safety and effectiveness.

Marc Hoskins
Regulatory Affairs

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Marc Hoskins
Regulatory Affairs
Söhniks Endoscopy, Inc.
930 Blue Gentian Road, Suite 1400
Eagan, Minnesota 55121

FEB 0 7 2003

Re: K023783
Trade Name: Söhniks
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: II
Product Code: HRX
Dated: November 1, 2002
Received: November 12, 2002

Dear Mr. Hoskins:

We have reviewed your Section 510(k) premarket 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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 (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K023783

Device Name: Arthroscope

Indications for Use:

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DO NOT WRITE BELOW THIS LINE

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhern

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K023783

(Optional Format 3-10-98)