510(k) Summary

General Company Information

Schoelly Imaging, Inc.
173 Grove Street
Worcester, MA 01605
Boni S. Bonneville, Office Administrator
508-425-6989

MAR 0 2 2007

General Device Information

Product Name: Flexilux II Endoscope

Common Name: Endoscope

Classification: Cystoscope, Diagnostic, Product Code: FAJ, Regulation number 876.1500
Hysteroscope and Accessories Product code: HIH, Regulation number 884.1720

Predicate Devices Schölly Laparoscope for General and Plastic Surgery (K992437)
ASAP Endoscope for Obstetrics and Gynecology (K031974)
ASAP Endoscope for Gastroenterology and Urology (K031141)

Indications for Use:

The Flexilux II Cystoscope is - like the predicate device – used to permit direct viewing of the male urethra, prostate, and bladder for purpose of performing diagnostic and surgical procedures.

The Flexilux II Hysteroscope is – like the predicate device - used to illuminate and visualize the cervical canal and the uterine cavity for the purpose of performing diagnostic and surgical procedures.

Product Description:

The Flexilux II Hysteroscope and Cystoscope (herein after; Flexilux II Endoscope) are rigid type endoscopes with traditional compact objectives and rod-lens system.

The basic design of the Flexilux II Endoscope is similar to those legally available for sale in the U.S.A... It consists of an eyepiece and the body with light guide and rod-lens system. The body is designed of an outer and an inner tube of surgical stainless steel. The light carrying fibers are sandwiched between these tubes. The inner tube of the body contains the rod-lens system.

Safety and Performance:

The specifications and intended use of the Flexilux II Endoscope is the same to those of the claimed predicate devices. There are no significant differences between the Flexilux II Endoscope and the claimed predicates in design or conditions of intended use.

The Flexilux II Endoscope is constructed of materials of the same specifications as the predicate devices to ensure biocompatibility. The Flexilux II Endoscope conforms to applicable ISO standards.

The device will be sold non-sterile, to be sterilized prior to each procedure by the user. Substantial equivalence for this device was based on a comparison of labeling, physical and performance design characteristics as compared to the predicate devices, as well as on the results of testing to establish compliance with the standards for medical endoscopes and medical electrical equipment (DIN 58105; IEC 60601-2-18).

Conclusion:
In all respects, the Flexilux II Endoscope is substantially equivalent to one or more rigid endoscopes currently marketed in the USA. It is constructed of materials of the same specifications as the predicate devices to ensure biocompatibility and it conforms to applicable ISO standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Mr. James Bonneville
Operations Manager
Schoelly Imaging, Inc.
173 Grove Street
WORCESTER MA 01605

MAR 0 2 2007

Re: K060899
Trade/Device Name: Flexilux II Endoscope
Regulation Number: 21 CFR §884.1690
Regulation Name: Hysteroscope and accessories
Product Code: HIH
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Product Code: FAJ
Regulatory Class: II
Dated: February 11, 2007
Received: February 13, 2007

Dear Mr. Bonneville:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) 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 (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 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 one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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/industry/support/index.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

510(k) Number (if known): K060899

Device Name: Flexilux II Endoscope

Indications for Use:

The Cystoscope is used to visualize the body cavities, hollow organs and canals during diagnostic and, in conjunction with additional instruments, therapeutic procedures.

The Hysteroscope is used to permit direct viewing of the cervical canal and the uterine cavity for the purpose of performing diagnostic and surgical procedures.

Prescription Use X AND/OR Over-the -Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart D)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lagman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K060899