ATTACHMENT 7

K023633

DEC 31 2002

510(K) SUMMARY

(As required by 21 C.F.R. §§ 807.87(h), 807.92)

1. Manufacturer

SOVIS OPTIQUE
B.P. 1-77260 La Ferte-Sous
77640 Jouarre
France

2. Contact Person

Hugues Tariel
Marketing Manager
Saint-Gobain, parent company of Sovis Optique
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Fax: +33 (0)1 60 22 79 67
Mobile: +33 (0)6 80 99 93 42
hugues.tariel@saint-gobain.com

3. Device

   1. Trade or Proprietary Name: None

   2. Common Name: Endoscopic light cable (accessory to endoscope)

   3. Classification/Product Code: II FST

4. Intended Use

Sovis Optique's endoscopic light cable is designed to transmit light for illumination purposes from a remote source to an endoscope or similar surgical instrument. It is designed to be adjustable to major manufacturers' equipment.

5. Predicate Devices

Sovis Optique's endoscopic light cable is substantially equivalent to Universal Fiberoptic Repair's UFR Fiberoptic Light Cable (K972225).

6. Device Description

Sovis Optique's endoscopic light cable consists of two metal end fittings connected by a glass fiber bundle and a silicone sheath covering. The sheath is reinforced with a stainless steel spring. The protruding optical end is made from an independent piece of glass bonded to a stainless steel support for ease of replacement.

7. Summary of Technological Characteristics

The SOVIS universal fiber optic cable is substantially equivalent to the predicate device for the following reasons:

- They have the same intended use.
- They have the same indicated target population.
- They have the same environment of use.
- They have the same or similar design.
- They are made of similar materials.

The minor differences between SOVIS Optique cable and the UFR Cable are as follows:

- The Sovis cable has a reinforced sheath. The reinforcement is molded into the silicone, and therefore has no chance to get into contact with human tissues. As demonstrated by the results of the biocompatibility tests performed on the material, the silicone that may potentially contact patients poses no additional safety issues.
- The Sovis cable has an independent glass rod at the source end. The rod is made from the same components as CUDA or UFR product (i.e., glass, epoxy glue and stainless steel). There is thus no significant adverse effect on safety.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 31 2002

Sovis Optique
c/o Frances K. Wu
Hyman, Phelps & McNamara
700 Thirteenth Street, NW, Suite 1200
Washington, D.C. 20005

Re: K023633
Trade/Device Name: Sovis Optique's Endoscopic Cable
Regulation Number: 876.1500
Regulation Name: Endoscope and Accessories
Regulation Class: II
Product Code: FFS
Dated: October 29, 2002
Received: October 29, 2002

Dear Ms. Wu:

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 (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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. 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" (21CFR Part 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,

Miriam C. Provost

for 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

ATTACHMENT 9

INDICATIONS FOR USE STATEMENT

510(k) Number: K 023633

Device Name: Endoscopic light cable

Indications for Use: Sovis Optique's endoscopic light cable is designed to transmit light for illumination purposes from a remote source to an endoscope or similar surgical instrument. It can be adjusted to be compatible with major manufacturers' equipment.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K023633

Prescription Use ✓ OR Over-the-Counter Use ____
(Per 21 C.F.R. § 801.109)