

510(k) Summary

K 973611 Pg 1 of 2

SpectraScience™ Reusable Biopsy Forceps

Summary Prepared September 17, 1997

DEC - 2 1997

Submitter's Name and Address *SpectraScience™, Inc.*
3650 Annapolis Lane, Suite 101
Minneapolis, MN 55447-5434

Contact Person John G. Yager
Director, Quality Assurance and Regulatory Affairs
SpectraScience™, Inc.
3650 Annapolis Lane, Suite 101
Minneapolis, MN 55447-5434
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Device Name
Proprietary Name: *SpectraScience™ Reusable Biopsy Forceps*

Common Name: Reusable Biopsy Forceps

Classification Name: Gastroenterology-Urology Biopsy Instruments (21 CFR 876.1075)
(Class I exempt)

Predicate Device *SpectraScience™ Single Use Biopsy Forceps*

Device Description The current biopsy forceps design has not changed during its long course of past clinical utility. The standard hinged design utilizes cup-shaped jaws to bite or pinch off tissue with minimal complications while providing a viable tissue sample. The cup-shaped jaws also serve to hold the biopsy sample within the forceps until the tissue can be transferred to a biopsy container.

The proposed *SpectraScience™ Reusable Biopsy Forceps* uses the most basic of standard design. The mechanism of action of the *SpectraScience™* design is identical to predicate devices in that the same standard mechanical design, materials and sizes are utilized. Using essentially identical mechanisms of action and materials results in identical clinical performance.

The *SpectraSciences* design employs an adjunctive technological characteristic. The *SpectraScience* design incorporates an optical illumination fiber. The optical illumination fiber is intended to provide the endoscopist with additional light from a different angle compared to the endoscope's light source. In various anatomies under certain circumstances, the endoscope's light angle may not reveal critical structural contours which should be considered before a biopsy is

performed. The intent of the *SpectraSciences* device is to enhance visualization and thus result in more accurate and precise identification and location of the tissue to be sampled.

The employment of an optical illumination fiber does not change the forceps' mechanism of action, performance, nor biopsy technique when compared to using standard biopsy forceps. The *SpectraScience™* Reusable Biopsy Forceps illuminates automatically once the forceps jaws are opened. No additional movements, techniques, or steps are required to deliver additional light to the targeted location. The application of adjunctive (xenon or intensity equivalent) light will have no adverse effect on tissue. The proven biocompatibility, safety and effectiveness, and clinical utility of fiberoptic illumination dates from prior to the 1976 amendments to present. Therefore, the application of adjunctive light via the *SpectraScience™* Reusable Biopsy Forceps does not negatively affect the safety or effectiveness of performing endoscopic biopsy. On the contrary, adjunctive light is intended to enhance the endoscopist's view of the location to be biopsied.

Product Testing
Biocompatibility

Biocompatibility is verified by vendor certifications and vendor biocompatibility testing.

Mechanical

Mechanical design, mechanisms of action, materials, dimensions, workmanship, operation, light transmittance, and light source connections are identical to predicate devices and therefore substantially equivalent.

Intended Use

The *SpectraScience™* Reusable Biopsy Forceps are designed specifically to collect tissue endoscopically for histologic examination. The instruments are intended for endoscopic gastrointestinal and urologic biopsy and should not be used for any purpose other than their intended function.

Conclusion

SpectraScience™, Inc., believes that their Reusable Biopsy Forceps are substantially equivalent to the predicate products due to the use of identical design, materials, indications for use and packaging.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 2 1997

Mr. John G. Yager
Director, Regulatory Affairs and Quality Assurance
Spectra Science Inc.
3650 Annapolis Lane, Suite 101
Minneapolis, Minnesota 55447

Re: K973611
Spectra Science™ Reusable Biopsy Forceps
Dated: September 17, 1997
Received: September 22, 1997
Regulatory Class: II
21 CFR §876.1500/Product Code: 78 GCT
21 CFR §876.1075/Product Code: 78 FCL

Dear Mr. Yager:

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 Current Good Manufacturing Practice requirement, 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. 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

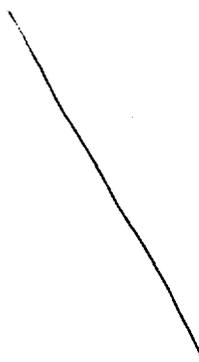
Enclosure

510(k) Number (if known): K97 3611

Device Name: *SpectraScience*TM Reusable Biopsy Forceps

Indications for Use:

The *SpectraScience*TM Reusable Biopsy Forceps are designed specifically to provide adjunctive illumination while collecting tissue endoscopically for histological examination. The instruments are intended for endoscopic gastrointestinal and urologic biopsy and should not be used for any purpose other than their intended function.



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Concurrence of CDRH, Office of Device Evaluation (ODE)

Dolan R. Rathbun
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K973611

Prescription Use:
(Per 21 CFR 801.109)

OR

Over-The-Counter Use:

(Facsimile)

(Optional Format 1-2-96)