K083788

Traditional 510(k)
Stonebuster Endoscopic System for Stone Removal (SESSR)
December 4, 2008

510(k) SUMMARY

MAR 3 2009

SPONSOR: Endo Optiks, Inc.
39 Sycamore Ave.
Little Silver, NJ 07739

CONTACT INFORMATION:

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DEVICE COMMON NAME:

Urological Catheter and Accessories

PREDICATE DEVICE:

- Boston Scientific Corporation UASS Ureteral Access Sheath K022135
  (CFR 21 part 876.5130, Urological Catheter and Accessories)
- Bard Dual Lumen Ureteral Catheter K032521
  (CFR 21 part 876.5130, Urological Catheter and Accessories)

DEVICE DESCRIPTION

The Stonebuster Endoscopic System for Stone Removal (SESSR) Delivery Catheter is a sterile, single-use device comprised of one main component: a flexible triple lumen delivery catheter with three Luer-Lock delivery ports. This device is intended to provide access to the ureteral canal and to be used to guide the currently available visualization devices and accessory devices such as biopsy forceps, cytology brushes, stone retrieval baskets, etc. during endoscopic procedures.

The SESSR Delivery Catheter is introduced into the desired anatomical location through an ureteral access sheath with a minimum working channel diameter of 4.3mm. The distal tip of the SESSR is straight or bent at a minimum of 6.5 mm from the distal tip at 10 degrees providing the physician with (when using visualization devices) a wider field of view.

STATEMENT OF INTENDED USE OF THE CATHETER FOR ENDOSCOPY

The Stonebuster Endoscopic System for Stone Removal (SESSR) Catheter for Endoscopy is intended to provide access to the ureteral canal and to be used to guide the currently available visualization devices and accessory devices such as biopsy forceps, cytology brushes, stone retrieval baskets, etc. during endoscopic procedures.

The indications for use of the catheter are in urological applications.

EXECUTIVE SUMMARY

Device Description

The Stonebuster Endoscopic System for Stone Removal (SESSR) Delivery Catheter is a sterile, single-use device comprised of one main component: a flexible triple lumen delivery catheter with three Luer-Lock delivery ports. This device is intended to provide access to the ureteral canal and to be used to guide the currently available visualization devices and accessory devices (such as biopsy forceps, cytology brushes, stone retrieval baskets, etc.) during endoscopic procedures.

The Stonebuster Endoscopic System for Stone Removal (SESSR) Delivery Catheter is introduced into the desired anatomical location through an access sheath with a minimum working channel diameter of 4.3mm. The distal tip of the Stonebuster Endoscopic System for Stone Removal (SESSR) is straight or bent at a minimum of 6.5 mm from the distal tip at 10 degrees providing the physician with (when using visualization devices) a wider field of view.

Table 1, provided below, is a comparison of the Endo Optiks Stonebuster Endoscopic System for Stone Removal (SESSR) device, Bards' Dual Lumen Ureteral Catheter and the Boston Scientific Ureteral Access Sheath Set (UASS). The similarities and differences between these devices are discussed in further detail in Section 12, Substantial Equivalence Discussion.

Item/Description	Bard Device	BSC Device	**Endo Optiks** Stonebuster Endoscopic System for Stone Removal (SESSR)
FDA 510(k) #	K032521	K022135	N/A
Indications for Use	allow access to and navigation of a torturous ureter using standard endoscopic techniques	The UASS is indicated for use in endoscopic procedures to facilitate the passage of endoscopes, urological instruments and for the injection of fluids into the urinary tract percutanously and retrograde.	To provide access to the ureteral canal and to be used to guide the currently available visualization devices and accessory devices, such as biopsy forceps, cytology brushes, stone retrieval baskets, etc. during endoscopic procedures
Shaft Material	Polyurethane	N/A	Pellethane 75D
Hub Material	Polyurethane	N/A	Pellethane 80A
Provided Sterile	Yes	Yes	Yes
Single Use	Yes	Yes	Yes
No. of Multiple Lumens	2	N/A	3

Table 1

Sterility Testing & Shelf Life

The Stonebuster Endoscopic System for Stone Removal (SESSR) catheter is provided sterile to the customer. The Stonebuster Endoscopic System for Stone Removal (SESSR) will be sterilized using ethylene oxide (EtO). Endo Optiks has contracted with STS Life Sciences Division of Ethox, located in Rush, NY to perform the sterilization. A full cycle, single lot batch validation was completed and the product found to be sterile using ethylene oxide (EtO) gas. The reports of these results are included in Section 14.1.

The shelf life of this product is currently set at six months. Samples of the product will be segregated and monitored periodically to ensure product sterility and that the device is fully functional. Results of these observations will be used to adjust the length of time the product will be permitted on the shelf.

CONCLUSION:

Endo Optiks, Inc. has reviewed the intended use, specifications for performance and bench test results conducted with the Stonebuster Endoscopic System for Stone Removal (SESSR), Catheter for Endoscopy, and finds that it is substantially equivalent to Bards' Dual Lumen Ureteral Catheter and the Boston Scientific Ureteral Access Sheath Set .

The Endo Optiks Stonebuster Endoscopic System for Stone Removal (SESSR) Catheter for Endoscopy is as safe and effective as the predicate devices. Any differences that have been identified between the devices are believed to be insignificant with respect to safety and effectiveness. Further details may be found in the table of similarities and differences located in Section 12.1 Substantial Equivalence Discussion. Endo Optiks believes there are no significant differences and no new questions of safety and effectiveness relative to the technological specifications and intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 3 2009

Mr. Donald Watson
QA/RA Manager
Endo Optiks, Inc.
39 Sycamore Avenue
LITTLE SILVER NJ 07739

Re: K083788
Trade/Device Name: Stonebuster Endoscopic System for Stone Removal (SESSR)
Regulation Number: 21 CFR 876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: II
Product Code: EYB
Dated: February 16, 2009
Received: February 20, 2009

Dear Mr. Watson:

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

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufactures, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry.suppot/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K083788

Device Name: Endo Optiks Stonebuster Endoscopic System for Stone Removal (SESSR)

Indications for Use:

The Stonebuster Endoscopic System for Stone Removal (SESSR) Catheter for Endoscopy is intended to provide access to the ureteral canal and to be used to guide the currently available visualization devices and accessory devices such as biopsy forceps, cytology brushes, stone retrieval baskets, etc. during endoscopic procedures.

The indications for use of the catheter are in urological applications.

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K083788

Prescription Use ✓
(Per 21 CFR 801.109)