DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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November 13, 2015

Boston Scientific Corporation
% Dave Yungvirt
CEO
Third Party Review Group, LLC
45 Rockefeller Plaza, Suite 2000
New York, NY 10111

Re: K153049
Trade/Device Name: LithoVue System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FGB
Dated: November 5, 2015
Received: November 9, 2015

Dear Dave Yungvirt,

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-

related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K153049

Device Name
LithoVue System

Indications for Use *(Describe)*
The LithoVue System is intended to be used to visualize organs, cavities and canals in the urinary tract (urethra, bladder, ureter, calyces and renal papillae) via transurethral or percutaneous access routes. It can also be used in conjunction with endoscopic accessories to perform various diagnostic and therapeutic procedures in the urinary tract.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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SECTION 6 510K SUMMARY

510(k) Summary for LithoVue™ System

A. Date Prepared

August 12, 2015

B. Sponsor

Boston Scientific Corporation
Urology and Women's Health Division
100 Boston Scientific Way
Marlborough, MA 01756

C. Contact

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D. Device Name

Trade name:	LithoVue System
Common usual/name:	Digital Flexible Ureteroscope
Classification:	FGB – Ureteroscope and accessories, flexible/rigid 21 CFR 876.1500, Class II

E. Predicate Device(s)

Trade name:	DUR-Digital Ureteroscope and Choledochoscope (DUR-D)
Common usual/name:	Ureteroscope and Accessories, Flexible/Rigid
Classification:	FGB – Endoscope, associated accessories 21 CFR 876.1500, Class II
Premarket Notification:	ACMI, K060269

and

Trade name:	Olympus URF-V (cleared as the Video Ureteroscope, NTSC)
Common usual/name:	Ureteroscope and Accessories, Flexible/Rigid
Classification:	FGB – Endoscope, associated accessories 21 CFR 876.1500, Class II

Premarket Notification: Olympus, K033651

F. Device Description

The LithoVue™ System is a software-controlled digital flexible ureteroscope system that consists of the LithoVue System Workstation (Touch PC with installed Interface Box and Cart) and the LithoVue Single-Use Digital Flexible Ureteroscope (sterile, single-use disposable).

The LithoVue System is designed to allow physicians to access, visualize, and perform procedures in the urinary tract, using appropriate accessory devices (e.g., baskets, laser fibers, forceps).

G. Intended Use

The LithoVue System is intended to be used to visualize organs, cavities and canals in the urinary tract (urethra, bladder, ureter, calyces and renal papillae) via transurethral or percutaneous access routes. It can also be used in conjunction with endoscopic accessories to perform various diagnostic and therapeutic procedures in the urinary tract.

This Intended Use is equivalent to that for the predicates, which are also used to perform various diagnostic and therapeutic procedures in the urinary tract using additional accessories.

H. Technological Characteristics

The LithoVue System has the same technological characteristics and fundamental design as the predicate devices. The LithoVue System and the predicate devices are all designed to provide real-time images to the physician in order to facilitate diagnostic and therapeutic procedures in the urinary tract.

The main difference between the LithoVue System and the predicate devices is reusability. The LithoVue Single-Use Digital Flexible Ureteroscope is single-use, while the predicate devices are reusable.

I. Substantial Equivalence

A direct comparison of key characteristics demonstrates that the LithoVue System is substantially equivalent to the predicate devices in terms of intended use, technological characteristics, and performance characteristics. The differences between the LithoVue System and predicate devices do not alter suitability of the proposed device for its intended use.

J. Performance Testing (Bench Evaluation)

Boston Scientific has conducted performance testing with LithoVue Flexscope samples aged at T=0 and T=3 months accelerated aged.

The following testing was completed to demonstrate the LithoVue System functions as intended:

- Working Distance Resolution in Air – Near, Typical and Far
- Field of View in Air
- Direction of View
- Image Orientation
- Contrast Sensitivity
- Image Signal to Noise
- Uniformity of Image Brightness
- Total Flux Available at Tip
- Image Latency
- Automatic Light Control (ALC)
- ALC Response Time
- Width of Insertion Portion Distal Tip
- Maximum Width of Insertion Portion (Overall Shaft Diameter and Size Designation)
- Working Length (Shaft Length)
- Minimum Instrument Channel Width
- Tortuous Path Ability
- Surface and Edges
- SUD Working Channel Freedom from Leakage
- SUD Shaft Leakage
- Torsional Resistance of Tip
- Tip Column Strength
- Shaft Flexural Resistance
- Maximum Angle of Deflection
- Bend Radius
- Secondary Deflection
- Deflection Life Cycling
- Shaft to Handle Tensile Strength
- Tip to Shaft Tensile Strength
- Handle to Active Deflection Torque Angle at Break
- Umbilicus to Handle Tensile Strength
- Umbilicus to Connector Tensile Strength
- Critical Shaft Bend Radius
- Shaft Bend Fatigue
- SUD Durability (Procedure Duration)
- SUD Mechanical Durability
- Neutral Position Marking
- Deflection Direction Marking
- Lever Force
- Connector Retention Strength
- Laser Aiming Beam Compatibility
- Laser Lithotripsy Compatibility
- Radiopacity
- Working Channel Connection Compatibility
- Maximum Endotherapy Tool Blind Insertion Distance
- Working Channel Length
- Monitor and Switcher Compatibility
- SUD Packaging Integrity
- SUD Package Seal Strength
- Photobiologic Safety per IEC 62471
- Software verification and validation

Biocompatibility of the LithoVue Single-Use Digital Flexible Ureteroscope was evaluated in accordance with ISO 10993-1:2009 for the body contact category of "Surface – Mucosal Membrane" with a contact duration of "Limited (< 24 hours)". The following tests were performed, as recommended: Cytotoxicity, Irritation, Sensitization, USP Physiochemical <661>, and Latex. All evaluation acceptance criteria were met.

Electrical safety testing of the System was evaluated in accordance with IEC 60601-1 (2005) Edition 3, IEC 60601-1-2 (2007) Edition 3, IEC 60601-1-4 (2000), Edition 1.1 Consolidated Edition, and IEC 60601-2-18 (2009), Edition 3. All evaluation acceptance criteria were met.

The results of the performance testing demonstrate that the LithoVue System is considered safe and effective for its intended use.