DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 7, 2016

EndoCure Technologies, Inc.
% E.J. Smith
Consultant
Smith Associates
1468 Harwell Avenue
Crofton, MD 21114

Re: K161147
Trade/Device Name: EndoCure Model EUR078A
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: FBN
Dated: April 20, 2016
Received: April 22, 2016

Dear E.J. Smith,

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,

Herbert P. Lerner -S

for 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)*
K161147

Device Name
EndoCure Model EUR078A

Indications for Use *(Describe)*

The EndoCure Model EUR078A has been designed for endoscopic observation and diagnosis within both the urinary tract (ureter, renal pelvis, and renal calyx) and biliary tract (common bile duct and hepatic duct). Therapeutic endoscopic procedures using various kinds of accessories are also possible, and include the ability to extract or fragment stones within these organs.

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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510(k) Summary
807.92C

SPONSOR **807.92(a)(1)**

Company name:	EndoCure Technologies, Inc.
Company Address:	5801 Ammendale Road, Suite
	Beltsville, MD 20705
Telephone Number:	301-937-8848
Contact Person:	Charles J. Neff (Vice President
Summary Preparation Date:	Operations) April 19, 2016

DEVICE NAME **807.92(A)(2)**

Trade Name:	EndoCure Model EUR078A
Common/Usual Name:	Flexible Endoscope
Classification Name:	Endoscopes and Accessories
Regulation Number:	21 CFR 876.1500
Product Code:	FBN
Device Class:	Class II

PREDICATE DEVICE **807.92(a)(3)**

Company	Product	510(k) Number
Olympus, Inc.	Ureterorenofiberscope/Choledochofiberscope	K912120

DEVICE DESCRIPTION **807.92(a)(4)**

EndoCure Model EUR078A is used during the examination / procedure as an ureteroscope. The ureteroscope is an instrument for examining the inside of the urinary tract. The ureteroscope is used to see beyond the bladder into the ureters, the tubes that carry urine from the kidneys to the bladder. Through the ureteroscope, the doctor can see a stone in the ureter and then remove it with a small basket at the end of a wire inserted through an extra channel in the

ureteroscope. Another way to treat a stone through an ureteroscope is to extend a flexible fiber through the scope up to the stone and then, with a laser beam projected through the fiber, break the stone into smaller pieces that can then pass out of the body in the urine. The EndoCure Model EUR078A ureteroscope is not designed for or intended to be used with electro-surgical (cautery) devices due to the metal distal tip.

DEVICE INDICATIONS FOR USE **807.92(A)(5)**

The EndoCure Model EUR078A has been designed for endoscopic observation and diagnosis within both the urinary tract (ureter, renal pelvis, and renal calyx) and biliary tract (common bile duct and hepatic duct). Therapeutic endoscopic procedures using various kinds of accessories are also possible, and include the ability to extract or fragment stones within these organs.

COMPARISON OF TECHNICAL CHARACTERISTICS **807.92(A)(6)**

Parameters	EndoCure Model EUR078A	Olympus Corporation URF-P2 Ureterorenofiberscope/ Choledochofiberscope	Similarities and Differences
510(k) Number	K141866	K912120	N/A
Intended Use	The EndoCure Model EUR078A has been designed for endoscopic observation and diagnosis within both the urinary tract (ureter, renal pelvis, and renal calyx) and biliary tract (common bile duct and hepatic duct). Therapeutic endoscopic procedures using various kinds of accessories are also possible, and include the ability to extract or fragment stones within these organs.	The Olympus URF Type P2 has been designed for endoscopic observation and diagnosis within both the urinary tract (ureter, renal pelvis, and renal calyx) and biliary tract (common bile duct and hepatic duct). Therapeutic endoscopic procedures using various kinds of accessories are also possible, and include the ability to extract or fragment stones within these organs.	Substantially equivalent indications for use
Field of View	90 degree	90 degree	Identical
Depth of View	1-50mm	1-50mm	Identical
Optical System	Fiberoptic Bundle	Fiberoptic Bundle	Identical
Distal End Outer	7.3 French (2.43mm)	9.3 French (3.1mm)	Difference in distal

Diameter			end outer diameter
Insertion Tube O.D.	8.4 French (2.8mm)	9.9 French (3.3mm)	Difference in insertion tube O.D.
Bending Angulation	Up:270/Down:270	Up:180/Down:180	Difference in bending angulation
Channel Inner Diameter	1.2mm	1.2mm	Identical
Working Length	700mm	700mm	Identical

Nonclinical Testing

Safety Testing

- ISO 10993-5 Biological Evaluation of Medical Devices – Part 5: Tests for In Vitro Cytotoxicity (ISO MEM Elution Assay with L-929 Mouse Fibroblast Cells)
- ISO 10993-10 Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Skin Sensitization (Intracutaneous Reactivity Test) (ISO Guinea Pig Maximization Sensitization Test)
- ISO 10993-10 Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Skin Sensitization (Acute Systemic Injection Test)
- ISO 10993-11: Biological Evaluation of Medical devices – Part 11: Test for Systemic Toxicity
- IEC 60601-1:2005 + CORR. 1 (2006) + CORR. 2 (2007) + AM1 (2012) 0r IEC 60601-1: 2012 Medical electrical equipment Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2007 Third Edition, Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests
- IEC 60601-2-18 Medical electrical equipment Part 2: Particular requirements for the basic safety and essential performance of endoscopic equipment

Performance testing

- FTIR and SEM Analysis
- Angulation Flex Bench test
- ISO 8600-3 Optics and Optical Instruments – Medical endoscopes and endoscopic accessories – Part 3: Determination of field of view and direction of view of endoscopes with optics.

- ISO 8600-4 Optics and Optical Instruments – Medical endoscopes and endoscopic accessories – Part 4: Determination of maximum width of insertion portion.

CONCLUSION **807.92(B)(3)**

The EndoCure Model EUR078A is substantially equivalent to the predicate device in intended use, materials and design. Safety and performance testing to ISO 8600-3 and ISO 8600-4 and biocompatibility testing to ISO 10993 Standards concluded that the device does not introduce significant questions of safety and efficacy and is substantially equivalent to the predicate.