DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 15, 2014

Enroxtech Incorporated
Mr. Lewis Ward
L.W. Ward and Associates Incorporated
4655 Kirkwood Court
Boulder, Colorado 80301

Re: K141330
Trade/Device Name: Endo-Cord
Regulation Number: 21 CFR 878.4580
Regulation Name: Surgical lamp
Regulatory Class: Class II
Product Code: FST
Dated: October 31, 2014
Received: November 5, 2014

Dear Mr. Ward:

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" (21CFR 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,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical 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)*
K141330

Device Name
Endo-Cord

Indications for Use *(Describe)*
This device is intended to transmit light for illumination purposes from the light source to endoscopes.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary, Section 807.92(a)(2)

Submitted by	Enroxtech, Inc. 4605 S. Denice Drive Englewood, CO 80111

Contact Person	Lewis Ward L.W. Ward and Associates, Inc. 4655 Kirkwood Court Boulder, CO 80301 303-530-3279 303-530-4774 Fax lwward@qwest.net

Date Prepared	April 30, 2014

Product Name	Endo-Cord

Classification	21 CFR 878.4580, Class II Light, Surgical, Fiberoptic Product Code: FST General and Plastic Surgery Panel

Intended Use	This device is intended to transmit light for illumination purposes from the light source to endoscopes.

Technological Characteristics	A 5mm fiber-optic light transmitting core with durable protective sleeve and stainless steel couplings at each end. One coupling is for the light source and the opposite end for connection to an endoscope. The core is inserted into a durable and reusable silicone rubber sheath. One length is available: 7.5 Feet Field replaceable fiber-optic core.

Non-clinical Testing	A cleaning validation performed meets AAMI TIR30 Cleaning of Reusable Medical Devices standard. Steam sterilization validation supports a cycle of a Prevacuum, 130° C, 4 minute exposure, 20 minute drying cycle. Sterilization and Sterility Assurance 10^{-6}.

Light Transmission Properties of the Endo-Cord is substantially equivalent to the predicate Sunoptics cord.

Results Table:

	High		Medium		Low	
	Endo-Cord	Sunoptics	Endo-Cord	Sunoptics	Endo-Cord	Sunoptics
Range	639-658	614-621	311-316	303-306	28-28	27-27
Average	650	618	314	305	28	27
Difference from Sunoptics	5.0%		2.8%		3.6%	

Conclusion:

The Endo-Cord intensity is substantially equivalent to the Sunoptics predicate fiber-optic cord. The average high intensity of the Endo-Cord is within 5% of the predicate Sunoptics cord. The average medium intensity is within 2.8% difference from the Sunoptics cord intensity. The average low intensity is within 3.6% of the Sunoptics

Substantial Equivalence	The Endroxtech Endo-Cord is substantially equivalent to the Cuda Products Co. Fiber Optic Cable (K901035)based on intended use, technology, materials, and light transmission.

Key Features Comparison

Feature	Enroxtech Inc. Endo-Cord	Cuda Products Co. Fiber-Optic Cable, K901035 (predicate)
Size	5 mm	3.0 and 5.0 mm
Sheathing	Silicone, reusable	Silicone, reusable
Fiber-optic light transmission	Glass fibers	Glass fibers
Length	90 inches	95.5 inches
Fiber-optic core replacement	Field replaceable by user	Factory replaceable only
End coupling	• Universal configuration • Adapters commercially available	• Universal configuration • Adapters available from manufacturer
Sterilization Method	Steam autoclave	Steam autoclave Cold soak