FDA

FDA Home[3] Medical Devices[4] Databases[5]

Establishment Registration & Device Listing

1 result found for **Establishment Registration or Business Trade Name :** *sunoptic tech*
Establishment Registration or FEI Number : *1035968*

New Search[6]

Establishment Name	▲7 ▼8	Registration Number	Current Registration Yr
SUNOPTIC TECHNOLOGIES, LLC[9]	FL/USA	1035968	2018

- Light Source, Fiberoptic, Routine - BRAND: Cuda; CUDA PRODUCTS CO. LIGHT SOURCES; Customer Brand: Sunoptics Surgical[10] — Contract Manufacturer; Manufacturer
- Light, Surgical, Floor Standing - BRAND: Cuda; Customer Brand: MODEL M300 LIGHT SOURCE; Sunoptics Surgical[11] — Contract Manufacturer; Manufacturer
- Light Source, Photographic, Fiberoptic - BRAND: Cuda; Customer Brand: FIBEROPTIC; FOR ENDOSCOPE; ILLUMINATOR; Sunoptics Surgical[12] — Contract Manufacturer; Manufacturer
- Light Source, Fiberoptic, Routine - BRAND: Cuda; Customer Brand: FIBEROPTIC; FOR ENDOSCOPE; ILLUMINATOR; Sunoptics Surgical[13] — Contract Manufacturer; Manufacturer
- Image, Illumination, Fiberoptic, For Endoscope - BRAND: Cuda; Customer Brand: FIBEROPTIC; FOR ENDOSCOPE; ILLUMINATOR; Sunoptics Surgical[14] — Contract Manufacturer; Manufacturer
- Illuminator, Fiberoptic, Surgical Field - BRAND: Cuda; Customer Brand: FIBEROPTIC; FOR ENDOSCOPE; ILLUMINATOR; Sunoptics Surgical[15] — Contract Manufacturer; Manufacturer
- Laparoscope, Gynecologic (And Accessories) - BRAND: Cuda; Customer Brand: FIBEROPTIC; FOR ENDOSCOPE; ILLUMINATOR; Sunoptics Surgical[16] — Contract Manufacturer; Manufacturer
- Light, Surgical Headlight - BRAND: Cuda; Customer Brand: FIBEROPTIC HEADLIGHT SYSTEM; Sunoptics Surgical[17] — Contract Manufacturer; Manufacturer
- Light, Surgical, Fiberoptic - CUDA SURGICAL HEADLIGHT[18] — Contract Manufacturer; Manufacturer
- Camera, Television, Endoscopic, Without Audio - BRAND: Sunoptics Surgical[19] — Contract Manufacturer; Manufacturer
- Light, Surgical, Fiberoptic - BRAND: Cuda; Customer Brand: Sunoptics Surgical[20] — Contract Manufacturer; Manufacturer
- Light, Surgical, Fiberoptic - BRAND: Cuda; Customer Brand: Light, Surgic Fiberoptic; Sunoptics Surgical[21] — Contract Manufacturer; Manufacturer
- Light Source, Fiberoptic, Routine - BRAND: Cuda; Customer Brand: Sunoptics Surgical[22] — Contract Manufacturer; Manufacturer
- Headlamp, Operating, Battery-Operated - LED HEADLAMP WITH BATTERY-PACK[23] — Contract Manufacturer; Manufacturer
- Retractor, Fiberoptic - Lumiere Light Cable[24] — Contract Manufacturer; Manufacturer

Can't find what you're looking for? Try a new search[25]

Links on this page:

1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
2. http://www.addthis.com/bookmark.php
3. http://www.fda.gov/default.htm
4. https://www.fda.gov/MedicalDevices/default.htm
5. https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/default.htm
6. ../cfrl/rl.cfm
7. ../cfrl/rl.cfm?start_search=1&establishmentName=sunoptic%20tech®Num=&StateName=&CountryName=&RegistrationNumber=1035968&OwnerOperatorNumber=
8. ../cfrl/rl.cfm?start_search=1&establishmentName=sunoptic%20tech®Num=&StateName=&CountryName=&RegistrationNumber=1035968&OwnerOperatorNumber=
9. ./rl.cfm?rid=297
10. ./rl.cfm?lid=142&lpcd=FCW
11. ./rl.cfm?lid=144&lpcd=FSS
12. ./rl.cfm?lid=145&lpcd=FCR
13. ./rl.cfm?lid=145&lpcd=FCW
14. ./rl.cfm?lid=145&lpcd=FFS
15. ./rl.cfm?lid=145&lpcd=HBI
16. ./rl.cfm?lid=145&lpcd=HET

FDA

Establishment Registration & Device Listing

New Search Back To Search Results

Proprietary Name:	BRAND; Sunoptics Surgical
Classification Name:	CAMERA, TELEVISION, ENDOSCOPIC, WITHOUT AUDIO
Product Code:	FWF[6]
Device Class:	1
Regulation Number:	878.4160[7]
Medical Specialty:	General & Plastic Surgery
Registered Establishment Name:	SUNOPTIC TECHNOLOGIES, LLC[8]
Registered Establishment Number:	1035968
Owner/Operator:	SUNOPTIC TECHNOLOGIES, LLC[9]
Owner/Operator Number:	1035968
Establishment Operations:	Contract Manufacturer; Manufacturer

Links on this page:

1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
2. http://www.addthis.com/bookmark.php
3. http://www.fda.gov/default.htm
4. https://www.fda.gov/MedicalDevices/default.htm
5. https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/default.htm
6. ../cfPCD/classification.cfm?ID=5425
7. ../cfCFR/CFRsearch.cfm?FR=878.4160
8. ../cfRL/rl.cfm?rid=297
9. ../cfRL/rl.cfm?start_search=1&OwnerOperatorNumber=1035968

Page Last Updated: 02/19/2018

Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Русский | العربية | Kreyòl Ayisyen | Français | Polski | Português | Italiano | Deutsch | 日本語 | فارسی | English

FDA

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

USA.gov

For Government For Press

FDA

FDA Home[3] Medical Devices[4] Databases[5]

Establishment Registration & Device Listing

New Search Back To Search Results

Proprietary Name:	LED HEADLAMP WITH BATTERY-PACK
Classification Name:	HEADLAMP, OPERATING, BATTERY-OPERATED
Product Code:	HPP[6]
Device Class:	1
Regulation Number:	886.4335[7]
Medical Specialty:	Ophthalmic
Registered Establishment Name:	SUNOPTIC TECHNOLOGIES, LLC[8]
Registered Establishment Number:	1035968
Owner/Operator:	SUNOPTIC TECHNOLOGIES, LLC[9]
Owner/Operator Number:	1035968
Establishment Operations:	Contract Manufacturer; Manufacturer

Links on this page:

1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
2. http://www.addthis.com/bookmark.php
3. http://www.fda.gov/default.htm
4. https://www.fda.gov/MedicalDevices/default.htm
5. https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/default.htm
6. ../cfPCD/classification.cfm?ID=4203
7. ../cfCFR/CFRsearch.cfm?FR=886.4335
8. ../cfRL/rl.cfm?rid=297
9. ../cfRL/rl.cfm?start_search=1&OwnerOperatorNumber=1035968

Page Last Updated: 02/19/2018

Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Русский | العربية | Kreyòl Ayisyen | Français | Polski | Português | Italiano | Deutsch | 日本語 | فارسی | English

FDA

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

FDA

Establishment Registration & Device Listing

New Search Back To Search Results

Proprietary Name:	Lumiere Light Cable
Classification Name:	RETRACTOR, FIBEROPTIC
Product Code:	FDG[6]
Device Class:	1
Regulation Number:	876.4530[7]
Medical Specialty:	Gastroenterology
Registered Establishment Name:	SUNOPTIC TECHNOLOGIES, LLC[8]
Registered Establishment Number:	1035968
Owner/Operator:	SUNOPTIC TECHNOLOGIES, LLC[9]
Owner/Operator Number:	1035968
Establishment Operations:	Contract Manufacturer; Manufacturer

Links on this page:

1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
2. http://www.addthis.com/bookmark.php
3. http://www.fda.gov/default.htm
4. https://www.fda.gov/MedicalDevices/default.htm
5. https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/default.htm
6. ../cfPCD/classification.cfm?ID=1741
7. ../cfCFR/CFRsearch.cfm?FR=876.4530
8. ../cfRL/rl.cfm?rid=297
9. ../cfRL/rl.cfm?start_search=1&OwnerOperatorNumber=1035968

Page Last Updated: 02/19/2018

Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.
Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Русский | العربية | Kreyòl Ayisyen | Français | Polski | Português | Italiano | Deutsch | 日本語 | فارسی | English

FDA

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
8757 Georgia Avenue
Silver Spring MD 20910

JUN 22 [illegible]

Ms. Cynthia Arcusa
Office Manager
CUDA Products Corporation
High-Technology Fiberoptics
6000 Powers Avenue
Jacksonville, Florida 32217-2279

Re: K893491
Models M2-150, M2-150T, M3-150, M2-150-300,
and M2-300-300 Lightsources
Regulatory Class: II
Model I-150 Lightsource
Regulatory Class: I
Dated: April 28, 1989
Received: May 4, 1989

Dear Ms. Arcusa:

We have reviewed your Section 510(k) notification of intent to market the devices referenced above and we have determined that these devices are substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market the devices, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act). The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

The Model I-150 Lightsource, as a microscope light, is classified into class I. As stated in the Federal Register on September 12, 1980, Vol. 45, No. 179, FR page No. 60590, microscope lights are subject to general controls, but are exempt from good manufacturing practice regulations with the exception of the requirements concerning records and complaint files.

The device models which are classified (see above) into class II (Performance Standards) may be subject to additional controls. Existing major regulations affecting your devices can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your devices in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under the Radiation Control for Health and Safety Act of 1968, or other Federal Laws or Regulations.

This letter immediately will allow you to begin marketing your devices as described. An FDA finding of substantial equivalence of your devices to a pre-amendments device results in a classification for your devices and permits your devices to proceed to the market, but it does not mean that FDA approves your devices. Therefore, you may not promote or in any way represent your devices or their labeling as being approved by FDA. If you desire specific advice on the labeling for your devices please contact the Division of Compliance Operations, Regulatory Guidance Branch (HFZ-323) at (301) 427-8040. Other general information on your responsibilities under the Act, may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

Carl A. Larson

Carl A. Larson, Ph.D.
Director, Division of Surgical
and Rehabilitation Devices
Office of Device Evaluation
Center for Devices and
Radiological Health