

510(k) Summary

Model 5197 SightLite

MAY 20 1997

General Information

Classifications: Class II

Trade Name: Clarus Model 5197 SightLite

Submitter: Clarus Medical Systems, Inc.
1000 Boone Avenue North #100
Minneapolis, Minnesota 55427

Contact: Dale Sappenfield
Vice President Engineering and Quality
(612) 525-8400

Substantially Equivalent and Predicate Devices

RapiScope™ Manual Light Source, manufactured by Cook Critical Care

Device Description

The Clarus Model 5197 SightLite is a hand held illumination device for endoscopy. The device has a means of attaching a legally marketed optical assembly manufactured by Clarus Medical Systems that is sold separately. The image connector on the endoscope attaches to the optical assembly. The male illumination receptacle on the endoscope attaches to the female receptacle on the Model 5197 SightLite. The power source is four 1.5 volt AA lithium batteries. The illumination source is a Tungsten Halogen lamp.

The SightLite is intended for multiple use. It is sealed for cleaning and disinfecting.

The optical assembly used with the SightLite endoscopic light source is a separate, legally marketed, Clarus Medical Systems device that can be attached to the SightLite by means of a machined clasp that is an intricate part of the SightLite.

Intended Use

The Clarus Model 5197 SightLite is intended as a illumination source for endoscopes. These endoscopes would be legally marketed Clarus Medical Systems devices. The SightLite is intended for multiple use. It is sold non-sterile.

Testing

Biocompatibility testing was performed on all exposed materials used in the construction of the SightLite. All materials passed biocompatibility testing and are suitable for this application.

Other testing included cold disinfectant (glutaraldehyde) exposure testing, liquid leak testing, battery life testing, dimensional measurements and visual examination for workmanship. All testing of the product yielded acceptable results.

Summary of Substantial Equivalence

The Clarus Model 5197 SightLite is indicated for use as an illumination source for endoscopes. These endoscopes would be legally marketed Clarus endoscopes. The Clarus SightLite is intended for multiple use.

The Clarus SightLite is substantially equivalent to the Cook Critical Care RapiScope Manual Light Source due to the design, method of use, materials used and methods of construction. The size and packaging are also equivalent. Additionally, the Cook Critical Care RapiScope is manufactured by Clarus Medical Systems for Cook.

Due to the similarity of materials, test results and methods of use to the predicate device, Clarus believes this product does not raise any new safety or effectiveness issues.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 20 1997

Mr. Dale Sappenfield
Vice President, Engineering and Quality
Clarus Medical Systems, Inc.
1000 Boone Avenue North, #100
Minneapolis, Minnesota 55427

Re: K971455
Clarus SightLite Model #5197
Dated: March 17, 1997
Received: April 21, 1997
Regulatory class: II
21 CFR §876.1500/Product code: 78 FTI

Dear Mr. Sappenfield:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4616. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

Lillian Yiu, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K971455

Device Name: CLARUS 5197 SIGHT LIGHT

Indications For Use:

ILLUMINATION SOURCE FOR CLARUS ENDOSCOPES.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert P. Sallberg
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K971455

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use