

Cogent Light Technologies 510(k) Premarket Notification for the SolarTec™ Source 270

DEC 23 1998

K 983714

ATTACHMENT No. 6 (510(k) SUMMARY OF SAFETY AND EFFECTIVENESS)

Safety

The Subject Device is designed with a safety interlock on the lamp replacement door. If the cover is opened, the power to the device will be interrupted.

The Subject Device is cooled with a forced air fan to prevent the temperature of the unit from exceeding a safe level. If in the event that the fan malfunctions and/or fails to operate properly and the internal temperature of the device exceeds the engineered specifications, the device is designed with an internal thermal protection mechanism that automatically shuts off the power to the lamp.

The lamp and power source may fail passively (i.e., just not turn on, or just go out). Typically, lamp and power source defects do not result in lamps going out during a surgical case. It is more likely that a lamp cannot be turned on during preparation for a surgical case. The consequences to the user is an inconvenience and a time delay. However, it is expected to result in no adverse medical condition in the patient.

To minimize such inconveniences, the Subject Device contains a user replaceable lamp fixture. Cogent Light encourages the operators to have a spare lamp available on site.

The lamp may fail in a non-passive mode, resulting in an audible sound. This sound may startle the user. Due to the inherent nature of all high intensity lamps, including those found in the Predicate Devices, it is impossible to guarantee against all such failures, although they are rare. To minimize such events, the Subject Device has incorporated several safety features into the product design. These safety features include:

- a) The lamp is never operated beyond its specified power range,
- b) The lamp life is limited to approximately 1000 hours by analog circuitry. This limit is significantly below the safe rated life expectancy of the lamp (approximately 4000 hours) as stated by the lamp manufacturer,
- c) The enclosure has interior structures (baffles), which will dampen the sound level and confine any debris which might result from the non-passive lamp failure.

The Subject Device will meet the following product safety standards:

- a) IEC601-1-2:1993 (Class B) - Medical electrical equipment Part 1: General requirements for safety

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2. Collateral Standard: Electromagnetic compatibility - Requirements and tests,

- b) IEC601-2-18:1996 - Medical electrical equipment Part 2: Particular requirements for the safety of endoscopic equipment
- c) UL2601-1 2nd ed. Standard for Safety Part 1: General Requirements for safety.

Effectiveness

Metal halide arc lamps produce light that is spectrally similar to sunlight. The color of the light that is actually delivered to an endoscope, surgical headlight, or surgical instrument, is determined by optical coatings and the transmissive properties of the light delivery system.

The Subject Device used with a Cogent Light single fiberoptic cable typically produces a uniform output image. The output image is independent of the intensity of the light source. By contrast, other commercial fiber bundles and illuminators produce non-uniform images due to the construction of the bundles and optics in the illuminators. Any application involving direct illumination (e.g. surgical headlamp) uniform illumination is a plus.

Fiber bundles have been the standard for light delivery. Due to the transmissive properties of their materials, they will attenuate more in the blue than red region of the spectrum, producing a more yellow light. Cogent Light single fiberoptic cables, used as part of the Subject Device, transmits white light uniformly throughout the visible spectrum.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Wayne Smith
Vice President of Operations
Cogent Light Technologies, Inc.
26145 Technology Drive
Santa Clarita, CA 91355-1137

Re: K983714
Solar Tec™ Source 270
Dated: October 15, 1998
Received: October 21, 1998
Regulatory Class: II
21 CFR 876.1500/Procode: 78 FFS

Dear Mr. Smith

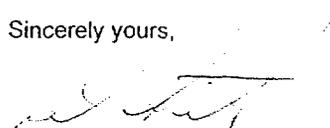
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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). 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 (Pre-market 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 Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS 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) 594-4613. 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/dsma/dsmamain.html>".

Sincerely yours,


Capt. Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

ATTACHMENT No. 5 (Indications for Use)

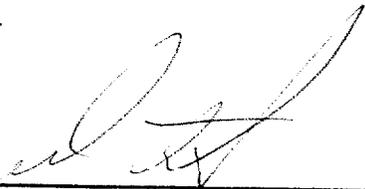
510(k) Number (if known): K983714

Device Name: SolarTec™ Source 270

The SolarTec™ Source 270 System is intended for use:

1. To provide visible light for with various rigid or flexible endoscopes, other lighted tools, and surgical headlamps that contain fiber bundles or single fibers for illumination
2. In providing illumination for the purposes of allowing observation and manipulation of body cavities and tissues, hollow organs, and canals.
3. With applications that include, but are not limited to, headlights and/or externally illuminated endoscopes used in arthroscopy, bronchoscopy, gynecology, laparoscopy, obstetrics, oto-rhyno-laryngoscopy, urology, and vascular endoscopy as well as surgical headlights used in various open surgical procedures.

Prescription Use ✓



(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K983714