K993314

Abbreviated Premarket Notification
Synthes Light Guide

DEC - 6 1999

II. 510(k) Summary

Submitted by: *Synthes (USA)*
1303 Goshen Parkway
West Chester, PA 19380

Contact Person: *Jonathan Gilbert*

Date Prepared: *September 22,1999*

Proprietary Name: *Synthes Light Guide*

Common Name: *Light Source Accessory*

Classification Name: 21 CFR §878.4580 (surgical lamp)

Predicate Device: K971057 - Cogent Light XLS Illuminator System
Cogent Light Technologies, Inc.
26145 Technology Drive
Santa Clarita, CA 91355-1137

Description of the Device:
The subject Synthes Light Guide uses a single 'fiberoptic' quartz fiber encased by medical grade stainless steel to externally illuminate a surgical site during surgical procedures. This light carrier is connected via standard adapters to currently marketed fiberoptic light cables which are sequentially connected to currently marketed Xenon or Halogen light sources. The materials and components of the Synthes Light Guide do not have patient contact or body fluid contact and therefore biocompatibility testing is not applicable. The device is approximately 310mm in length and 6mm in diameter. It is designed to be affixed via clamps to a ring retractor system which positions the device above the surgical site during a surgical procedure. An engineering drawing of the Synthes Light Guide is included as Tab 1.

The Cogent Light XLS Illuminator System consists of a light source control box, which houses a Xenon lamp, power supply and connects to a fiberoptic cable. This light guide carrier of the XLS Illuminator, a single fiberoptic cable (single quartz fiber) is used as part of their system for transmitting light to a surgical site.

Comparison of Synthes Light Guide to Predicate Device		
	Synthes Light Guide	Cogent Light XLS Illuminator System fiberoptic cable
CHARACTERISTIC		
Intended use: provide illumination during surgery	YES	YES
Lamp Type	None. Used in conjunction with Halogen or Xenon sources	Used in conjunction with Xenon lamps
Lamp Rating	N/A	N/A

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 6 1999

Mr. Jonathan Gilbert
Senior Regulatory Affairs Associate
Synthes (USA)
1690 Russell Road
P.O. Box 1766
Paoli, Pennsylvania 19301-1262

Re: K993314
Trade Name: Synthes Light Guide
Regulatory Class: II
Product Code: FQP
Dated: October 1, 1999
Received: October 4, 1999

Dear Mr Gilbert:

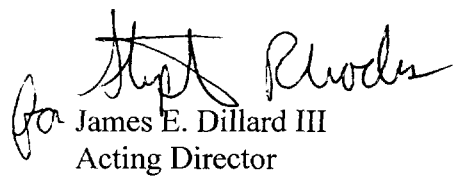
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 current Good Manufacturing Practice requirement, 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) 594-4595. 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,



James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

VII. INDICATIONS FOR USE STATEMENT

510(k) Number: (if known)

Device Name: Synthes Light Guide

Indications For Use: The Synthes Light Guide is intended to transmit light to illuminate a surgical site during surgical procedures

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR §801.109)

(Division Sign-Off)
Division of General, Restorative Devices
510(k) Number K993314