

K964005

JUN - 9 1997

### Section XI - Summary of Safety and Effectiveness

Date of Preparation: April 14, 1997

Device Name: Synergetics, Inc. Synerlight Fiber Optic Lightsource

Classification Name: Ophthalmic Endoilluminator 86 MPA

Manufacturer: Tayman Medical, Inc. located at 15 Foxhunt Drive, Chesterfield, Missouri 63017

Predicate Device: The Synergetics lightsource is substantially equivalent in intended use, safety and effectiveness and construction to the Dutch Ophthalmic, USA Xenon Illumination System catalog number 1266-X manufactured by Dutch Ophthalmic, USA (D.O.R.C.) located at Two Marshall Road, Kingston NH 03848. Telephone number (800) 753-8824.

Device Description: The Synergetics lightsource is a stand alone arc-lamp based lightsource that incorporates a standard connector mount used by most endoilluminators. It has a brightness control, accessory filter control and lamp life timer display.

Intended Use: The Synergetics Fiber Optic light Source is indicated for use during anterior and posterior vitreoretinal surgery to illuminate the eye.

### Clinical and Non-Clinical Similarities and Differences

Predicate D.O.R.C. Lightsource	New Synergetics, Inc. Lightsource	Safety and Effectiveness Information
The D.O.R.C., Inc. Fiber Optic Lightsource is indicated for use during anterior and posterior vitreoretinal surgery to illuminate the eye.	The Tayman Fiber Optic Lightsource is indicated for use during anterior and posterior vitreoretinal surgery to illuminate the eye.	There are no differences in regards to safety and effectiveness.
Filter Selection Knob - The filter selection knob is detented and turns an internal filter wheel that allows the user to select from up to six different accessory filters.	Filter Selection Knob - The filter selection knob is detented and turns an internal filter wheel that allows the user to select from up to six different accessory filters.	There are no differences in regards to safety and effectiveness.

Connector Mount - The connector mount is a standard design that accepts most commercially available endoilluminator light fibers. It has an internal detent that holds the light fiber in place and helps to confirm that the light fiber is fully inserted.

Brightness Control - The brightness control knob turns an internal light dimming wheel that allows the user to adjust the light output of the fiber. There is no front panel labeling that shows the knob position indicators in regards to the brightness control knob.

Lamp - The lamp is an arc-lamp based ILC 75 watt Cermax lamp with integral reflector. The Cermax lamp is manufactured by ILC Technology. It is a xenon lamp.

Connector Mount - The connector mount is a standard design that accepts most commercially available endoilluminator light fibers. It has an internal detent that holds the light fiber in place and helps to confirm that the light fiber is fully inserted.

Brightness Control - The brightness control knob, turns an internal light dimming wheel that allows the user to adjust the light output of the fiber. The brightness control knob has a small indicator arrow that aligns with the indicating artwork. The brightness artwork depicts the off, standard and high output settings. A red LED next to the high power label, an audible beep and a tactile detent will alert the user when the lightsource is used in the high power mode.

Lamp - The lamp is an arc-lamp based Welch Allyn 24 watt Hi-Lux lamp with integral reflector. The Hi-Lux lamp is manufactured by Welch Allyn Lighting Products Division. It is a metal-halide lamp.

There are no differences in regards to safety and effectiveness.

There are no differences in regards to safety and effectiveness as the relative differences are addressed by explicit product labeling and warning indicators.

There are no differences in regards to safety and effectiveness as this same Welch Allyn Hi-Lux lamp is currently used in other medical fiberoptic products such as the:

- Welch Allyn LCI 200 Integrated Illumination and Imaging System. This system is manufactured by Welch Allyn Lighting Products Division
- Storz Instrument Company, Inc. uses the same lamp in its Storz Premiere II Microsurgical System which is also used with endoilluminators in vitreo-retinal surgery.

## Accessory Filters

The D.O.R.C. lightsource is available with five different accessory filters. They are ordered at the time of initial purchase for factory installation. These filters are:

- 585 A Green Filter
- 585 B Yellow Filter
- 585 C Red Filter
- 585 D Blue Filter
- 585 E Daylight Filter

## Accessory Filters

The Synergetics lightsource incorporates five different imaging enhancing filters. These filters are installed at the factory. These filters are:

- Filter #1 - White light Filter
- Filter #2 - Triple-band filter
- Filter #3 - UV/Blue light filter
- Filter #4 - Blue narrow band filter
- Filter #5 - Green narrow band filter
- Filter #6 - Red narrow band Filter

The Synergetics #1 filter is equivalent to using the D.O.R.C. lightsource without any of its accessory filters. There is no difference in terms of the safety and effectiveness in regards to the filter #1 as it provides the basic white light output with UV and IR filtering. .

The Synergetics #2 triple band filter has no equivalent in the D.O.R.C. lightsource. There are no differences in terms of safety and effectiveness as this filter only serves to block the light output in the areas that are in between that of the primary colors; blue, green and red. This can only reduce the overall power output as compared to the #1 white light filter..

The Synergetics #3 UV/Blue light filter has no equivalent in the D.O.R.C. lightsource. The D.O.R.C. lightsource produces a substantial amount of light below 495nm and does not incorporate this UV/Blue light safety feature.

There is no differences in regards to safety and effectiveness of the Synergetics filters #4,#5 and #6 as they are just color filters that transmit a narrower spectrum in their particular color range than the color filters used in the D.O.R.C lightsource.

## Visible Light Output

The D.O.R.C. lightsource produces "white 5600<sup>0</sup>K temperature light. As tested by Tayman Medical the overall power output of the D.O.R.C. lightsource was 17.8mW.

## Visible Light Output

The Synergetics lightsource produces a "white" 5500<sup>0</sup> K temperature light. The overall power output potential of the Synergetics lightsource is 36.1mW's when using white light filter #1, a large fiber endoilluminator and the high power brightness range. When used in the standard power brightness range with a large fiber endoilluminator or the high power range with a small fiber endoilluminator the power output is approximately 15.0 mW. This power output is approximately the same power output as most existing vitreo-retinal lightsources. When used This filter provides the most light transmission and therefore all of the other filters would result in lower light output.

There are no differences in regards to safety and effectiveness as the extra power present in the lightsource is only used when it is attenuated by the use of small fiber endoilluminators, special image enhancing filters or when the specific surgical situations that requires and permits the use of this higher than standard power output are present. Various statements regarding the safe use of this lightsource in high power mode are provided in the device labeling and owners manual.

## UV Light Output

The D.O.C.R. lightsource produces a substantial amount of light below 420nm.

## UV Light Output

The Synergetics lightsource white light filter #1 blocks the lamps UV output below 420nm.

This filter provides the least UV attenuation and therefore the use of any of the other Synergetics Lightsource filters would result in even lower UV output.

The Synergetics lightsource also incorporates a UV/Blue light filter. This filter blocks the UV-blue light below 495nm and is for use in certain circumstances where it is desirable to have the UV-blue light component reduced even further than that achieved when using the white light filter # 1. This filter does result in a light output that is extremely yellow but there are times when this light quality versus additional safety is justified. Such instances may be when the surgeon will be spending a lot of time with the endoilluminator in close proximity to the retina. For example during membrane peeling procedures using an endoilluminator with integral pick. This UV/Blue light filter also incorporates the standard IR blocking as outlined below.

The UV/Blue light output is considerably less than the D.O.R.C. lightsource. Many studies have been done that show that the extended use of UV light below 420nm in vitreo-retinal illumination can cause phototoxicity damage to the eye. Therefore the illumination of the UV light below 420nm is critical to safe intraocular illumination. And, it is safer than the D.O.R.C. lightsource in this regard..

## IR Light Output

The unfiltered ILC lamp that the D.O.R.C lightsource uses is expensive and very inefficient for visible light only applications. Testing by Synergetics and product information supplied by ILC show that the unfiltered lamp produces almost 60% of its power output in the harmful I.R. range. This results in a lightsource that could be very dangerous if its internal I.R. filter were to break or is removed for some reason.

## IR Light Output

The Synergetics lightsource white light filter #1 blocks the lamps IR output above 700nm.

This filter provides the least IR attenuation and therefore the use of any of the other filters would result in even less IR output.

There is no difference in terms of the safety and effectiveness in regards to the IR output of the Synergetics lightsource as many studies have been done that show that the extended use of heat producing IR light above 700nm in vitreo-retinal illumination to be potentially dangerous to the eye. Therefore the Synergetics lightsource has been designed to eliminate the IR light above 700nm.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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Synergetics, Inc.  
Mr. James Taylor  
VP - Director of Quality Assurance  
c/o Tayman Medical, Inc.  
15 Foxhunt Drive  
Chesterfield, MO 63017

Re: K964005  
Trade Name: Synergetics Synerlight Fiber  
Optic Lightsource  
Regulatory Class: II  
Product Code: 86 MPA  
Dated: April 14, 1997  
Received: May 15, 1997

Dear Mr. Taylor:

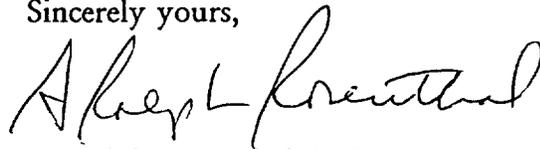
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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) 594-4613. 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 at (301) 443-6597.

Sincerely yours,



A. Ralph Rosenthal, M.D.  
Director  
Division of Ophthalmic Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number (if known): K964005

Device Name: Synergetics, Inc. Synerlight Fiber Optic Lightsource

Indications For Use: The Synergetics Fiber Optic Lightsource is indicated for use during anterior and posterior vitreoretinal surgery to illuminate the eye.

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Concurrence of CDRH, Office of Device Evaluation (ODE) :



(Division Sign-Off)  
Division of Ophthalmic Devices

510(k) Number K964005

Prescription Use X  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use     

(Optional Format 1-2-96)