**Premarket Notification**
**Infinitech, Inc.**
750 Goddard Avenue
Chesterfield, MO 63005
(314) 532-5667; (314) 532 8059 fax

K971950

## 510(k) SUMMARY OF SAFETY AND EFFICACY

The following information is submitted in accordance with the requirements of 21 CFR 807.92:

**Contact Person:** Alan T. Beckman, Vice President, RA/QA

**Date Prepared:** May 15, 1997

**Proprietary Names:** Infinitech Multi-Spot™ Slit Lamp Laser Adapter.

**Common/Usual Name:** Ophthalmic slit lamp laser accessory.

**Classification Name:** Ophthalmic Laser 21CFR §886.4390 (86HQF).

**Device Description/Intended Use:** The multi-spot slit lamp laser adapter is a non-powered reusable optical system which, when connected between the laser fiber and the slit lamp zoom optics, generates four spots in a square pattern. Through a rotary mechanism the user can select between single or multiple spot patterns. The multi-spot laser adapter mechanically mimics the fiber cable and will not effect or deactivate any existing safety interlocks. The lens system of the multi-spot adapter provides a one-to-one image of the laser fiber, therefore the spot size indicator on the zoom lens systems is not effected. The selection of single or multiple spot patterns also applies to the aiming beam, this gives the user direct and unambiguous feedback on which mode is selected before treatment begins.

**Safety:** There are three points which require special safety instructions:

Green Only. The multi-spot laser adapter may operate over 488- 650nm when in the single spot mode. However, the grating which generates the multi-spot pattern is optimized for 514-532nm. The manual reminds the user that the multi-spot pattern should only be used for "green only" treatments. This is not considered a limitation since "green only" is the wavelength of choice for proliferative retinopathy.

Calibration. The Multi-Spot optical systems consists of high efficiency optical elements. However, introduction of this system will require laser console calibration. The manual informs the user to have the laser calibrated after installation or removal of the device.

Output power in multi-spot mode. The multi-spot laser adapter "divides" the single spot energy into four spots, therefore each spot contains at the most one-fourth the displayed energy value. The user can compensate for this difference by increasing the displayed laser power, increasing the exposure time, or decreasing the spot size. Conversion tables are included in the users manual to show the relative trade-offs of power, exposure and spot size. Cautionary statements to instruct the user to lower the laser power before returning to single spot mode are included. Direct visualization of the aiming beam will provide a reminder as to the mode selected.

**Efficacy:** The multi-spot laser adapter can be used in a single or multi-spot mode. The multi-spot

laser adapter uses the laser's own fiber optic cable without modification. The focal plane of the multi-spot adapter corresponds to that of the fiber optic cable and the zoom lens system. Therefore there are no unexpected shifts in focus regardless of zoom range. The multi-spot laser adapter "divides" the single spot energy into four spots of equal energy. The 4 spots are positioned in a square pattern, nominally separated by 1 spot diameter. Efficacy is improved because 4 burns of equal intensity are produced with one exposure from the laser. This greatly speeds up the procedure and should reduce user and patient fatigue. With a single spot exposure, users find laying down a uniform pattern is difficult and the pattern is typically more random than a geometric in distribution. A 4-spot pattern improves the repeatability of burn distribution.

**Predicate Device:** The Multi-Spot™ Slit Lamp Adapter is substantially equivalent to the Coherent® System 920AD (K844357), the Alcon®/Biophysic™ Ophthalas® (K number unknown), and Alcon Ophthlas® 532 Laser (K Number Unknown). A device comparison chart illustrating substantial equivalence is attached.

**Predicate Comparison:** A chart comparing the Multi-Spot Adapter to the predicate devices, demonstrating substantial equivalence, is attached.

**Submitted by:**

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Alan T. Beckman

Attachment:
Device Comparison Chart

## Device Comparison Chart

| Device Characteristic | Coherent 920AD | Ophthalas 532 | Alcon/Biophysic Ophthalas | Infinitech Multi-Spot Adapter | |
|---|---|---|---|---|---|
| | | | | Single Spot Mode | Multi-Spot Mode |
| | | | | | |
| Device Type | Ophthalmic Laser | Ophthalmic Laser | Ophthalmic Laser | Ophthalmic Laser | Ophthalmic Laser |
| Ophthalmic Indications | Multiple | Multiple | Multiple | Multiple | Proliferative Retinopathy |
| Laser Energy Source | Argon/Krypton | Doubled Nd: YAG | Argon/Krypton | Argon/Krypton Doubled Nd: YAG | Argon Doubled Nd: YAG |
| Laser Energy Delivery | Single Spot | Single Spot | Single Spot | Single Spot | Multi-Spot (4 spots) |
| Spot Placement | Centered on Guide Beam | Centered on Guide Beam | Centered on Guide Beam | Centered on Guide Beam | Centered on Guide Beam |
| Laser Energy Intensity | Selected by Physician | Selected by Physician | Selected by Physician | Selected by Physician | Selected by Physician |
| Tissue Effect | Photocoagulation | Photocoagulation | Photocoagulation | Photocoagulation | Photocoagulation |
| Labeling per 21CRF 801.109? | YES | YES | YES | YES | YES |
| Labeling per 21CFR 1040.10? | YES | YES | YES | YES | YES |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Alan T. Beckman
Vice President, RA/QA
INFINITECH™
750 Goddard Avenue
Chesterfield, Missouri 63005

AUG - 1 1997

Re: K971950
Trade Name: Infinitech Multi-Sport Slit Lamp Laser Adapter
Regulatory Class: II
Product Code: HQF
Dated: May 27, 1997
Received: May 28, 1997

Dear Mr. Beckman:

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 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) 594-4595. 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,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K971950

Device Name: Infinitech Multi-Spot Slit Lamp Laser Adapter

Indications For Use:

The Multi-Spot Slit Lamp Laser Adapter has two functional modes available to the physician:

a single spot mode and a Multi-Spot (4 spot) mode. When the single spot mode is selected, the preexisting slit lamp laser apparatus is available for all treatment functions for which it was designed as a laser photocoagulator.

The multi-spot mode is intended for use with "Green-Only" (514-532nm) laser energy for panretinal photocoagulation in the treatment of proliferative retinopathy.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use____ OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

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