

Premarket Notification

OCT - 1 1997

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

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

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: July 2, 1997

Proprietary Names: Infinitech Bullet[®] Endo Illuminated Pick Manipulator

Common/Usual Name: Illuminated ophthalmic surgical instrument

Classification Name: Transilluminator, Class II per 21 CFR §886.1945, Product Code 86HJM.

Device Description/Intended Use: Hand-held illuminated pick and membrane delamination instrument for ophthalmic surgery.

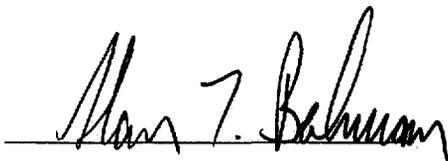
Safety: The instrument is constructed of commonly used materials for ophthalmic surgical instruments and is configured in a tool geometry familiar to surgeons. The patient contact materials raise no questions regarding toxicity or biocompatibility.

Effectiveness: The instrument is constructed of commonly used materials for ophthalmic surgical instruments and is configured in a common tool geometry.

Predicate Devices: Peregrine Surgical Ltd. Peregrine Wide Angle Light Pipe (K940393) and Peregrine Pic Manipulator (K940392).

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

Submitted by:



Alan T. Beckman

Device Comparison Chart

Device Characteristic	Peregrine Wide Angle Light Pipe	Peregrine Pic Manipulator	Infinitech Wide Angle Pick Manipulator
Device Type	Manual Wide Angle Fiber Optic Light	Manual Manipulator	Manual Manipulator With Wide Angle Fiber Optic Light
Indications for Use	Ophthalmic Surgery	Ophthalmic Surgery	Ophthalmic Surgery
Patient Contact Materials	Surgical Steel Surgical Fiber Optics	Surgical Steel	304 Stainless Steel Acrylic & Fluoropolymer
Sterilization Method	Not Known	Not Known	Validated EtO
Packaging	Not Known	Not Known	Validated Heat Sealed Tyvek
Labeling per 21CFR 801.109?	Not Known	Not Known	YES



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Alan T. Beckman
Vice President, RA/QA
Infinitech, Inc.
750 Goddard Avenue
Chesterfield, MO 63005

Re: K972506
Trade Name: Infinitech Bullet Endo Illuminated Pick Manipulator
Regulatory Class: II
Product Code: 86 HJM
Dated: July 2, 1997
Received: July 3, 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 (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.

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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/dsmamain.html>".

Sincerely yours,



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

Enclosure

Indications for Use

Infinitech Bullet® Endo Illuminated Pick Manipulator

The Pick Manipulator is a manual tool for aiding the procedural needs of the surgeon during ophthalmic surgery, such as tissue manipulation and membrane delamination.

There are no contraindications for the device.

Marsha L. Burke Nicholas

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K972506

Prescription Use Marsha L. Burke Nicholas
(Per 21CFR89.109)