JUN 2 9 2005

K051630

Insight Instruments, Inc.

3. 510(k) Summary

3.1 Date Prepared: April 19, 2005

3.2 Applicant:

Insight Instruments, Inc.
5400 S. Bryant Avenue
Sanford, FL 32773, USA
Phone: (407) 324 0388
Fax: (407) 324 0522
Contact: Michael Annen, VP Engineering & Mfg.

3.3 Device Name

Proprietary Name: *Super View Disposable BIOM Lens Set*
Common Name: Diagnostic Lens
Classification Name: Lens, Contact, Polymethylmethacrylate, Diagnostic

3.4 Device Classification: HJK, Class II, 21 CFR 886.1385

3.5 Device Description: The *Super View Disposable BIOM Lens Set(s)* consists of multiple sterile, disposable, thermoplastic lenses for both contact and non-contact use in conjunction with an operating microscope equipped with a BIOM wide-angle viewing system.

3.6 Intended Use: The Diagnostic Lenses are intended to be used in conjunction with an operating microscope as a surgical optic to improve visualization of the ocular fundus, vitreous and retinal structures. Diagnostic lenses are indicated for use during vitreoretinal surgical procedures.

3.7 Summary and comparison of technological characteristics:

	Insight Instruments, Inc. Diagnostic Lenses	**Ocular Instrument, Inc. Vitrectomy Lenses**
Materials	PMMA, Polystyrene, other thermoplastics	PMMA, Silicone, Glass, Quartz
Design	Contact lens has concave surface with corneal radius on one side, flat surface on other side. Non-contact lenses have spheric and aspheric surfaces and thermoplastic housings.	Contact lens has concave surface with corneal radius on one side, flat surface on other side. Other designs include biconcave, 20° and 30° prism lenses. Some designs may be used with a handle or scleral ring.
Sterility	Sterile disposable	Sterile disposable and Non-sterile reusable

3.6 Substantial Equivalence	The Insight Instruments, Inc. Diagnostic Lenses are equivalent in design, materials, classification and intended use and indications to vitrectomy lenses marketed by Ocular Instruments, Inc. cleared via 510(k) number K012096, 8/24/01.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 9 2005

Insight Instruments, Inc.
c/o Daniel W. Lehtonen
Responsible Third Party Official
Intertek Testing Services NA, Inc.
70 Codman Hill Rd.
Boxborough, MA 01719

Re: K051630
Trade/Device Name: Super View Disposable BIOM Lens Set
Regulation Number: 21 CFR 886.1385
Regulation Name: Polymethylmethacrylate (PMMA) diagnostic contact lens
Regulatory Class: Class II
Product Code: HJK
Dated: June 16, 2005
Received: June 17, 2005

Dear Lehtonen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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.

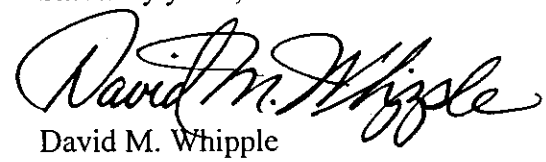
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (301) 827-8910. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



David M. Whipple
Acting Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2. Statement of Indications for Use

510(k) Number (if known): K051630

Device Name: Diagnostic Lenses

Indications for Use:

Allow visualization of the ocular fundus, vitreous, and retinal structures during vitreo-retinal surgery.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K051630