

K974522

Ophthalmic Technologies Inc.

FEB 25 1998

3D i-scan
510(k) Submission

510(k) Summary

(1) Submitter Information

Name: Ophthalmic Technologies Inc..

Address: 37 Kodiak Crescent, Unit 16
Downsview, Ontario M3J 3E5
Canada

Telephone Number: 416-631-9123

Contact Person: Dr. George Myers (Official
Correspondent)

Medsys Inc.
377 Rt 17 S
Hasbrouck Heights, NJ 07604
201-727-1703 Fax 201-727-1708

Date Prepared: November 7, 1997

(2) Name of Device:

Trade Name: 3D i-scan

Common Name: Program to convert Ultrasound scans to
perspective images.

Classification Name: System, Imaging, Ultrasonic,
Ophthalmic, (90IYO)

(3) Equivalent legally-marketed devices:

Life Imaging Systems Sirius, K961403

(4) Description

The 3D i-scan works in conjunction with the Ophthalmic Technologies Inc. (OTI) i-scan ophthalmic B-scan system. It automatically makes a series of 201 B-scans at different angles, and then combines them to produce a perspective image, called the "3D image."

Scanning is done through a closed eye-lid. The 3D i-scan consists of a computer and computer monitor, and a mechanical scan assembly which holds the B-scan ultrasonic scanner and rotates it at a speed synchronized with the lateral scanning rate of the probe. Ultrasonic gel is used

as a coupling medium between the transducer and the surface of the lid. The gel also prevents the rotary motion of the transducer from affecting the surface of the eye-lid. The computer system assembles the multiple images of the interior of the eye, all taken at a slightly different angle, and produces a three-dimensional representation of the interior of the eye on the computer monitor screen.

Software facilities are included for a number of types of image manipulation, such as slicing, changing orientation, zooming, and measurement of distances, areas, and volumes.

(5) Intended Use

The Ophthalmic Technologies Inc. (OTI) 3D i-scan is intended to be used as an accessory with the OTI i-scan Ophthalmic B-scan Ultrasound system (K960622) to provide a three-dimensional visualization of the interior of the globe. The device is indicated when it is desirable to have a three-dimensional depiction (perspective rendering) of the interior of the globe for diagnostic purposes.

(6) Technological characteristics

The device is virtually identical to the predicate device. The device is almost entirely a software system, except for the mechanical scan rotator. It uses a Macintosh computer in addition to the OTI i-scan system.

(b) Performance data

(1) Non-clinical tests

Electrical safety tests are provided for the scan rotator. All the other components are commercially-available computers and computer accessories.

(2) Clinical tests

A test of the measurement accuracy of the system, done by outside experts, is included.

A validation test of the imaging capabilities is included, as is the software validation test.

(3) Conclusions

The OTI 3D i-scan is equivalent in safety and efficacy to the legally-marketed predicate devices.



FEB 25 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850Ophthalmic Technologies, Inc.
George Myers
c/o Medsys, Inc.
377 Route 17 South
Hasbrouk Heights, NJ 08601Re: K974522
3D iscan (3D Ultrasound Ophthalmic Image Processing Software)
Dated: November 26, 1997
Received: December 2, 1997
Regulatory class: II
21 CFR 892.1560/Procode: 90 IYO

Dear Mr. Myers:

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) 594-4613. 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,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K974522

Device Name: 3D i-scan

Indications for Use:

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 810.109)

OR

Over-the-Counter Use _____

(Optional Format 1-2-96)

David L. Reardon
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K974522