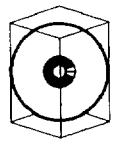

510(k) Summary of Safety and Effectiveness

Submitter Information: Applied Spectral Imaging
POB 101 Migdal Haemek, 10551, Israel
Phone: +972-6-6547567
Fax: +972-6-6547507

Corresponding Official: David Neustadter

Proprietary Name and Model: Retinal Cube

Common/Usual Name: Ophthalmic Digital Imaging System

Classification Name: AC Powered Ophthalmic Camera (21 CFR 886.1120)

Predicate Device: Topcon IMAGEnet 640 digital ophthalmic imaging system (k870039)

Device Description

The Retinal Cube is an accessory to a standard fundus camera which enables the acquisition, processing, and display of spectrally resolved images with high contrast visualization of blood vessels.

The Retinal Cube consists of the following three major components.

- The imager unit which mounts on a standard fundus camera and actually acquires the spectrally resolved images
- A controller unit which contains the electronics that control the imager
- A computer which performs display processing and provides the user interface for the system

The imager unit produces a three dimensional data set consisting of a spectrum for each pixel.

The 'data is processed using an algorithm which takes advantage of the spectral information to produce a two dimensional image containing high contrast visualization of the blood vessels.

Intended Use

The Retinal Cube is intended for use as an accessory to a fundus camera providing spectrally resolved imaging of the retina and optic disc and producing high contrast visualization of the blood vessels.

Comparison to Predicate Device

Comparison of relevant specification and performance parameters of the Retinal Cube and the predicate device:

	Retinal Cube	Predicate Device
Spatial Resolution	Fundus Camera Dependent	Fundus Camera Dependent
Grayscale Image Size	640x480 Pixels	640x480 Pixels
Color Image Size	320x240 Pixels	640x480 Pixels
Maximum Spectrally Resolved Image Size	320x240 Pixels	N/A
Spectral Resolution @ 500 nm	15 nm	Ordinary RGB Resolution, ~60 nm
Wavelength Bands	30 Bands, Typical	Ordinary RGB Image, 3 Bands
Maximum Acquisition Time	15 Sec	60 msec
Typical Data File Size	300KB Grayscale, 20MB Spectral[1]	300KB Grayscale, 900KB Color

Table 1: Comparison of the Retinal Cube and the predicate device

A comparison of the Retinal Cube and the predicate device shows that images produced by both devices are spatially resolved color images and use image enhancement algorithms. The Retinal Cube device provides images at a comparable spatial resolution to the predicate device, by adjusting the magnification on the fundus camera. Also, the Retinal Cube uses sophisticated image enhancement algorithms, enabled by higher spectral resolution of the acquired data. The deeper spectral information allows the Retinal Cube to create images showing blood vessel enhancement comparable to the predicate device.

Safety

The potential hazard of exposure of the patients retina to harmful levels of light is avoided by hardware limitations of the fundus camera light source.

Electrical safety hazards are avoided by compliance with the IEC 601-1 standard.

Mechanical safety hazards: The Retinal Cube contains no external moving parts or potentially hazardous elements such as sharp corners or edges. A Mechanical Safety Analysis was performed in a clinical setting, and no potential mechanical hazards were identified.

The risk of all potential software hazards is reduced through software verification and validation and bench testing.

Bench Data

The bench data indicate that the system meets its specifications and is able to produce the required spectral and spatial resolution and accuracy to produce high quality enhanced retinal images.

[1] Currently the entire matrix of data is saved and can be re-analyzed at a later time.

Clinical Data

The clinical data indicate that the system produces images with enhanced visualization of the blood vessels which are comparable to those produced by the predicate device.

Substantial Equivalence

As summarized in this document, the safety and effectiveness of the Retinal Cube are similar to that of the Topcon IMAGEnet 640. It is ASI's opinion that the Retinal Cube is substantially equivalent to its legally marketed predicate device in terms of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 12 1997

Michael Adel
Applied Spectral Imaging
POB 101
Migdal Haemek 10551
Israel

Re: K973950
Trade Name: Retinal Cube
Regulatory Class: II
Product Code: 86 HKI
Dated: October 14, 1997
Received: October 16, 1997

Dear Mr. Adel:

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) 594-4613. 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

510(k) Number (if known): K973950

Device Name: Retinal Cube

Indications For Use:

An accessory to a Fundus camera providing spectrally resolved images of the retina and optic disc and providing high contrast visualization of the blood vessels.

(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)

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K973950