SEP 2 3 2003

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

The assigned 510(k) number is: K032769

Submitted by: Steven E. Feldon, M.D.
President
Eye-deas, LLC
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Rochester, New York 14610

Date Prepared: July 21, 2003

Device Name

Proprietary Name:	EyesOPen Tonometer
Common Name:	Ocular Tonometer
Classification Name:	Tonometer, Manual

Substantial Equivalence

The Eye-deas EyesOPen tonometer is similar in indications, optical design and IOP calculation methodology to the Perkins tonometer.

The Eye-deas EyesOPen tonometer is similar in indications, size, user interface, microprocessor operation and solid-state force transducer design to the Tono-Pen 3 tonometer.

Device Description

The Eye-deas EyesOPen tonometer is a precision electronic tonometer, which measures intraocular pressure (IOP). The body of the instrument is specially designed to fit comfortably in the user's hand, facilitating fast and accurate measurements.

The EyesOPen tonometer contains a solid-state force transducer and a CMOS image transducer that together produces electrical signals from which intraocular pressure is derived. When sufficient valid readings are obtained an IOP reading is displayed on a liquid crystal display.

Under each of the four digits are bars. The bars correspond to the goodness of fit to a linear regression of pressure against applanated diameter. The regression coefficient is 95% or better if the first bar is

illuminated, 90%-95% if the second bar is illuminated, 80%-90% if the third bar is illuminated, or less than 80% if the fourth bar is illuminated.

Intended Use

The Eye-deas EyesOPen tonometer is used to measure the intraocular pressure (IOP) during routine eye examinations or when an increased IOP is suspected.

Substantial Equivalence Comparison – Perkins Tonometer

	EyesOPen tonometer	Perkins tonometer
Indication	Intraocular pressure (IOP) measurement	Same
Design	Hand-held microprocessor based	Hand-held manual dial
Force transducer	Solid state element	Spring and weight
Imaging transducer	Electronic imager	Operator's eye
IOP algorithm basis	Goldmann	Same
Calibration	None required	External weights
Contact tip	6mm glass coaxial	6 mm glass transverse
User interface	Briefly touched against eye	Held on patient's eye while dial is adjusted
Display	4 digit LCD	Scribed dial
Range of measurement	5 – 90 mmHg	5 –50 mmHg
Statistical reliability of the reading	The bars correspond to the goodness of fit to a linear regression of pressure against applanated diameter. The regression coefficient is 95% or better if the first bar is illuminated, 90%-95% if the second bar is illuminated, 80%-90% if the third bar is illuminated, or less than 80% if the fourth bar is illuminated.	No indication of reading reliability
Versatility	Patient can be in any position.	Same.
Weight (with batteries)	3 ounces	12.4 ounces
Dimensions	1" H x 1 ¼" W x 7 " L	1 ½" H x 1 ½" W x 11" L
Power source	2 ea 3.0 volt lithium batteries	4 ea. 1.5 volt AA batteries

Substantial Equivalence Comparison – Tono-Pen 3 Tonometer

	EyesOPen tonometer	Tono-Pen 3
Indication	Intraocular pressure (IOP) measurement	Same
Design	Hand-held microprocessor based	Same
Force Transducer	Solid-state	Same
Imaging Transducer	Electronic CMOS imager	No imaging elements
IOP calculation basis	Goldmann	Mackay-Marg
Calibration	None required	None required
Contact tip	6mm glass coaxial	3 mm stainless steel coaxial
Measurement technique	Briefly touched against eye	Same
User control	Single push button	Same
Single use sanitary tip cover	Required	Not required
Display	4 digit LCD	Same
Range of Measurement	5 – 90 mmHg	Same
Statistical Reliability	The bars correspond to the goodness of fit to a linear regression of pressure against applanated diameter. The regression coefficient is 95% or better if the first bar is illuminated, 90%-95% if the second bar is illuminated, 80%-90% if the third bar is illuminated, or less than 80% if the fourth bar is illuminated.	The bars correspond to standard deviation expressed as a percentage of the mean pressure. The first bar is illuminated at <5%, the second bar is illuminated at 5% to 10%, the third bar is illuminated at 10% to 20%, the fourth bar is illuminated at >20%.
Versatility	Patient can be in any position.	Same.
Weight (with batteries)	3 ounces	2.3 ounces
Dimensions	1" H x 1 ¼" W x 7 " L	1" H x 1" W x 7 3/4" L
Power Source	2 ea 3 volt lithium batteries	2 ea. 1/3N 3 volt lithium batteries

Performance Testing

Although not required to establish substantial equivalence, the EyesOPen tonometer was tested to establish baseline performance. The EyesOPen tonometer was tested on a simulated human eye. The EyesOPen tonometer performance was consistent with the performance of the predicate tonometer devices on this simulator.

Steven Feldon
Submitter's Signature

7-28-03
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 3 2003

Eye-deas, LLC
c/o Erin Sparnon
CITECH
5200 Butler Pike
Plymouth Meeting, PA 19462

Re: K032769
Trade/Device Name: EyesOPen Tonometer
Regulation Number: 21 CFR 886.1930
Regulation Name: Tonometer and accesories
Regulatory Class: Class II
Product Code: HKY
Dated: September 5, 2003
Received: September 8, 2003

Dear Ms. Sparnon:

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) 594-4613. 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/dsma/dsmamain.html

Sincerely yours,

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

Enclosure

510(k) Number (if known): K032769
Device Name: EyesOPen tonometer (manual tonometer)

Indications for Use:

The EYE-deas EyesOPen tonometer is used to measure the intraocular pressure (IOP) during routine eye examinations or when an increased IOP is suspected. This device is intended for use by Ophthalmologists, Optometrists, and other trained medical professionals.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K032769

Prescription Use ✓ OR Over-the-Counter Use_____
(Per 21CFR801.109)