3/5/99

Summary of Safety and Efficacy

K984443

Date of Summary	March 3, 1999
Sponsor	Orbtek, Inc. 1977 W. North Temple Salt Lake City, UT 84106 , USA 801-320-9700
Contact Person	Pier Calacino Quality Assurance Manager
Name of Device	Orbscan II™ Keratometer
Class	Class II
Classification Name	AC Powered Keratoscope AC Powered SlitLamp Biomicroscope (886.1850)
Product Code	MXK Anterior Segment Analysis Device
Predicate Device	The predicate device is the original Orbscan manufactured by Orbtek, Inc., and cleared for marketing by FDA on 07/06/94 with premarket notification number K940647.
Intended Use	The Orbscan II Keratometer is intended to scan, map and display the geometry of the anterior segment of the eye.

Device Description

The Orbscan II is a non-invasive, diagnostic system that measures and displays the anterior segment geometry of the eye. The system consists of an optical head, power supply and CPU. The optical head projects light through moving slit shaped apertures. The slit images are projected onto the eye at equi-distant angles from a central optical axis. A video camera placed on the optical axis records the images of the slits as they pass over the eye. The location of each slit at each position is determined during the system calibration.

During an examination, the slits are stepped across the cornea and an image of the cornea at each slit location is recorded. The CPU processes the images by using edge detection algorithms to determine the location of all of the edges the light strikes during the exam. Through direct triangulation, the elevation and curvature for the various surfaces is determined. Corneal thickness, anterior chamber depth and elevation of the iris and lens can then be determined by subtracting the surfaces.

This anterior segment information is displayed graphically to a user in the form of colored maps. These maps display variations in height and thickness numerically as well as with gradations in color. The graded colors allow for easier visualization of true

measurements and how they relate to elevation and thickness of the eye geometry. The maps can be displayed individually or in several combinations. They can also be customized by the user for their specific examination needs. The Orbscan operates on a Windows™ based user interface and operating system that allows for ease of operation and system control. The CPU used with the Orbscan is a standard, high-speed PC type computer. Other peripherals may include a display monitor, a mouse pointing device and a printer for hard copies of the maps, should the user desire them.

To enhance repeatability, an optional placido pattern can be attached to the Orbscan. The placido pattern provides slope data for the anterior surface of the eye. The slope data obtained from using the placido pattern is combined with the elevation data as measured with triangulation. Tests on both test objects and human subjects have shown that the reproducibility has been enhanced from +/- .005mm without the placido to +/- .003 mm with the placido pattern.

The device is non-invasive and only contacts the patient on his/her chin and forehead. The other concerns for safety are the light output and electrical safety. The light output is of an eyesafe intensity and wavelength. Electrical safety is provided by packaging which is compliant to accepted safety standards, and medically safe power sources which isolate the patient from hazardous voltages and current.

The device is proven effective in measuring the anterior geometry of the eye through internal company and independent clinical studies.

Product Comparison

Feature	Orbscan	Orbscan II
Field of view	10 x 14 mm	same
Axis range	0 to 360 degrees	same
Dioptric range	9 to 99 Diopters	same
Resolution	0.10 Diopters	same
Reproducibility	+/- 0.025 mm	+/- 0.003 mm[1]
Acquisition head	scanning slit HiRes video CCD camera Fully coated optics Coaxially fixation light Optical Positioning Aid	same
Additional Hardware		Backlit placido pattern[2] Relocation of Power supply to Self contained box[3]
Power Requirements	110/120 volt AC, 50/60 Hz 220/240 volt AC, 50/60 Hz	same
Dimensions	24" x 34" footprint	same
Cpu[4]	80486 33 MHz 4 Mb Ram	Intel Pentium technology 400 MHz or greater typ 128Mb Ram

[1] Surfaces measured with Placido pattern attached.

[2] The Placido Pattern provides slope data, which, when integrated with true elevation data yields better surface curvature calculations. The pattern is back illuminated with highly diffused LED light sources and is attached to the front of the Orbscan II without modification. The pattern does not come in contact with the patient and is electrically isolated for safety.

[3] The power supply was originally located in the cabinet that contained the CPU. The previous location was determined to not be as safe due to the fact that computer housings are frequently accessed by non-technical individuals. The new location allows more room for a medically approved power supply and it isolates the device from uncontrolled grounding. This arrangement also prevents un-authorized access to the device.

[4] Increased computing capability allowed the ability to process the increased amount of data points. Orbscan took approximately 3-5 min to process the anterior corneal surface only. Orbscan II processes all information in less than 1 ½ min.

Results	Anterior surface topography[5] of the cornea	Anterior surface topography Posterior Surface topography Full Corneal Pachymetry Elevation of the iris Elevation of the Lens Depth of the Anterior Chamber

[5] The term Topography is used to include the two terms of Elevation and curvature.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 5 1999

Mr. Pier Calacino
Quality Assurance Manager
ORBTEK, Inc.
1977 West North Temple
Salt Lake City, UT 84116

Re: K984443
Trade Name: AC-powered Slitlamp Biomicroscope
Regulatory Class: II
Product Code: MXK
Dated: January 22, 1999
Received: January 25, 1999

Dear Mr. Calacino:

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): K984443

Device Name: Orbscan II

Indications For Use:

The Orbscan II intended use is for scanning, mapping and displaying the geometry of the anterior segment of the eye.

(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 Devices
510(k) Number K984443

Prescription Use___ OR Over-The-Counter Use___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)