510(k): K100954

510(k) Summary

FEB 25 2011

Submitter:	Apeliotus Vision Science, Inc. 1456 N. Morningside Drive, NE Atlanta, Georgia 30306
Contact Person:	John G. Edwards, CEO Apeliotus Vision Science, Inc. 1456 N. Morningside Drive, NE Atlanta, Georgia 30306 Phone: 404-875-9561 Email: jedwards@apeliotus.com
Date Prepared:	February 18, 2011
Trade Name:	Adapt™
Classification:	886.1050
Product Codes:	HJW
Predicate Device:	Goldmann-Weekers adaptometer
Device Description:	The Adapt™ is an AC-powered, automated, adaptometer (biophotometer).
Intended Use:	The Adapt™ is an AC powered, automated adaptometer (biophotometer) intended to measure the time for retinal adaptation after exposure to an adapting light.
Comparison of Technological Characteristics:	The Adapt™ is technologically substantially equivalent to the predicate in being AC-powered and having a similar design with photobleach light and stimulus light to evaluate dark adaptation. The Adapt™ differs from the predicate primarily in that it is controlled by software.
Verification & Validation Testing Testing:	Verification testing was conducted on the following subsystems: Flash, Stimulus, Fixation Light, Patient Input & Patient Management, Infrared Camera, Refractive Correction, and Chin Rest. Software verification/validation was conducted and computer control and integration was verified. Calibration & Alignment were verified. Testing demonstrated that the device met product specifications and performance requirements. Validation testing, including conducting dark adaptation testing on subjects, was also conducted. All results met final requirements and demonstrate substantial equivalence to the predicate device.

510(k) Summary (Continued)

Clinical Performance Testing:	An Agreement Study was conducted comparing the Adapt™ against the predicate with 12 adults having a range of eye health status. Dark adaptation speed as characterized by both the rod-cone break and the rod intercept parameters was found to be highly correlated between the two instruments. A Precision Study was conducted among 14 adults with normal retinal health and 8 patients with age-related macular degeneration (AMD). Each participant was tested twice separated by two weeks. Dark adaptation speed was characterized using both the rod-cone break and rod intercept parameters. For comparison, similar measurements were made on a separate group of 6 normal adults using the predicate. Dark adaptation speeds for the Adapt™ were highly correlated between the first and second visits for both parameters, and the precision of the Adapt™ was comparable to the predicate.
Conclusion:	By comparison of design features and by testing the Adapt™, we conclude it is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Apeliotus Vision Science, Inc.
c/o Mr. John G. Edwards
Chief Executive Officer
1456 N. Morningside Drive, NE
Atlanta, GA 30306

FEB 25 2011

Re: K100954
Trade/Device Name: Adapt™
Regulation Number: 21 CFR 886.1050
Regulation Name: Adaptometer (biophotometer)
Regulatory Class: I Exempt
Product Code: OUM
Dated: February 18, 2011
Received: February 22, 2011

Dear Mr. Edwards:

We have reviewed your premarket notification submission and have found this device to be exempt from the premarket notification requirements of the Federal Food, Drug, and Cosmetic Act (Act). Therefore, you may immediately begin marketing this device as described in your premarket notification.

The final classification regulation for your device appears in Title 21 of the Code of Federal Regulations (CFR) 21 CFR 886.1050. We suggest that you review this regulation since it may grant other exemptions from certain general controls of the Act. Your device classification regulation name, regulatory class, and product code are shown above. When listing your device with the Food and Drug Administration, please use this product code.

In the future, new but substantially equivalent devices which fall within the above classification regulation name and meet the classification criteria may be marketed without sending a premarket notification submission to the Food and Drug Administration. We suggest, however, that you review 21 CFR Section 886.9 to determine whether or not your new device (s) meets the limitations of exemption from Section 510(k) of the Act.

If you have any questions regarding this letter, please contact Daryl Kaufman at (301) 796-6620 or the Division of Small Manufacturers, International and Consumer Assistance at its toll free number (800) 638-2041 or (301) 796-7100, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html."

Sincerely yours,

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use Statement

510(k) Number: k100954

Device Name: Adapt™

Indications For Use:

The Adapt™ is an AC powered, automated adaptometer (biophotometer) intended to measure the time for retinal adaptation after exposure to an adapting light.

Prescription Use (Part 21 CFR 801 Subpart D) ___X___ 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, Neurological and Ear, Nose and Throat Devices

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