K000731

MAR 31 2000

510(k) SUMMARY

Talia Technology, Ltd.'s
CRTA Retinal Thickness Analyzer

Submitter's Name, Address, Telephone Number, And Contact Persons

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Date Prepared: [Insert Date]

Name of the Device: CRTA Retinal Thickness Analyzer

Name/Address of Sponsor: Talia Technology, Ltd.
106 Industrial Zone
Mevaseret Zion, Israel
Phone: 011-972-2-534-4023
Facsimile: 011-972-2-534-4486

Common or Usual Name: Retinal Thickness Analyzer

Classification Name: Ophthalmoscope, AC-Powered (Product Code HLI)

Predicate Devices: Talia Technology, Ltd. RTA Retinal Thickness Analyzer (K964137).

Intended Use:

The CRTA Retinal Thickness Analyzer is a computerized slitlamp biomicroscope that is intended to provide manual and computerized tomography of

the retina *in vivo*. The CRTA scans successive slit images of the fundus, without the need for a contact lens, to determine the thickness and the inner structure of the retina, both by observation of the slit images and by computer analysis of these images. It is indicated for assessing the area and location of retinal thickness abnormalities, such as thickening due to macular edema and atrophy associated with degenerative diseases, and for visualizing other retinal pathologies.

Device Description, Principles of Operation, and Technological Characteristics:

The CRTA is a modification of the previously cleared RTA retinal Thickness Analyzer. As with the RTA, the Talia CRTA is a compuetrized electro-optical system comprised of two primary components, namely the optical head and the computer system. The main elements of the optical head include laser and conventional light sources, optics, a scanner, and digital cameras.

The CRTA is a computerized slitlamp biomicroscope that provides manual and computerized tomography of the retina *in vivo*. The CRTA scans successive slit images of the fundus to determine the thickness and the inner structure of the retina, both by observation of the slit images and by computer analysis of these images.

The CRTA uses a helium neon laser source that emits green light at a wavelength of 543.3 nm. The beam is focused into a thin slit and, by means of a mirror, is directed toward the eye. The scanner and optics then detect the image of the illuminated portion of the retina and transmit the image to the digital camera.

The digital camera then captures the image, where it can then be stored and analyzed by the computer system.

Substantial Equivalence:

The CRTA is a modification of the previously cleared RTA retinal Thickness Analyzer. The only differences between the previously cleared RTA and the modified CRTA device are:

1. an increase in the scan area from 2 x 2 millimeters ("mm") to 3 x 3 mm;
2. use of a mouse-driven alignment control with an "xyz" stage motor drive system in place of the current joystick alignment control;
3. concurrent fundus and target focusing;
4. moveable focal targets in place of fixed targets;
5. redesign of the mechano-optics for compactness;
6. a change in the manufacturing process for the CRTA cover to polyurethane casting from vacuum forming;
7. reduction of the number and type of electrical component boards and placement of special electronics into the CRTA optical head, allowing the use of industry standard computers for control in place of the special design boards and power supply used in the RTA.

Through design control assessment, including verification and validation testing, Talia has demonstrated that the modifications to the CRTA do not alter the device's intended use or indications, nor have the principles of operation or technological characteristics been altered. As such, the Talia CRTA is substantially equivalent to the Talia RTA Retinal Thickness Analyzer.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 31 2000

Talia Technology, LTD
c/o Mr. Jonathan S. Kahan
Partner
HOGAN & HARSTSON L.L.P.
Columbia Square
555 Thirteenth Street, NW
Washington, DC 20004-1109

Re: K000731
Trade Name: Clinical Retinal Thickness Analyzer (CRTA)
Regulatory Class: II
Product Code: 86 HLJ
Regulation: 886.1570 (Ophthalmoscope)
Dated: March 6, 2000
Received: March 6, 2000

Dear Mr. Kahan:

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

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

INDICATIONS FOR USE

510(K) Number (if known): K000731

Device Name: CRTA Retinal Thickness Analyzer

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)

Geneette Beam

(Division Sign-off)

Division of Dental, Infection Control, and General Hospital Devices

510(k) Number K000731

Prescription Use ✓ OR Over-The-Counter Use_____

(Per 21 CFR 801.109)