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510(k) SUMMARY

Talia Technology Ltd.
RTA RETINAL THICKNESS ANALYZER

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

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Name of Device and Name/Address of Sponsor

RTA Retinal Thickness Analyzer

Talia Technology, Ltd.
106 Industrial Zone
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Common or Usual Name

Retinal Thickness Analyzer

Classification Name

AC-powered slitlamp biomicroscope

Predicate Devices

Talia's Laser Slit™ Slit Lamp Attachment (K930518)
Heidelberg Engineering's Heidelberg Retina Tomograph (K912891)
Humphrey Instruments' Optical Coherence Tomography (OCT) System (K944523)
Rodenstock Instrument's Scanning Laser Ophthalmoscope (K871268 and K882517)
Laser Diagnostic Technologies, Inc.'s Nerve Fiber Analyzer (K941705)
Laser Diagnostic Technologies, Inc.'s Topographic Scanning System TOPSS (923742)
Ophthalmic Imaging Systems, Inc.'s Glaucoma Scope (K913118)

Intended Use

The RTA is a computerized laser slitlamp biomicroscope that is intended to provide manual and computerized tomography of the retina *in vivo*. The RTA scans successive slit images on 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.

Technological Characteristics and Substantial Equivalence

The Talia RTA is a computerized electro-optical system comprised of two primary components, the optical head and the computer system. The main elements of the optical head include laser and conventional light sources, optics, a scanner, and three digital cameras.

The optical head has a 0.2 mW helium neon (HeNe) laser that emits green light at a wavelength of 543.5 nm. The beam is focused into a thin slit, 2.2 mm in length and 15 microns in width. The mirror directs the laser beam toward the eye, but permits simultaneous illumination with the conventional slit. The laser scans 10 slits of 2 mm length in each scan and can scan at a rate of 20 msec per slit for retinas. The stereo angle of the scan (the angle between the laser beam on the retina and the detector axis) can be set at 11.5° or 5.7°. The scan density (the distance between slits in the scan) is 200 microns for normal density and has a total scan area of 2 x 2 mm. The scan density for dense density is 100 microns and has a total scan area of 1 x 2 mm.

The computer system consists of the computer, peripheral boards, color monitor, printer, keyboard, mouse, footpedal, isolation transformer, and software. The RTA software is composed of two parts, the control software and the analysis software. The control software controls the operation of the RTA. For analysis of images to create thickness maps, it invokes the analysis software.

The RTA is substantially equivalent to the predicate devices in that it has the same intended use and operates on the same basic principle. The Talia RTA and its predicate devices are intended to project a beam of light onto a patient's eye in order to visualize details and provide measurements of various ocular structures. Like the RTA, the other predicate devices have a light source, optical system, scanner, and, with the exception of Talia's Laser Slit™, a computer that controls the operations of the device and analyzes the images and a monitor to display the images. With the RTA and its predicate devices, a beam of light is projected onto a patient's eye, the light is reflected according to the optics of the device, and, with the exception of the Laser Slit™, the resulting image or signal is processed by a computer system.

Performance Data

The safe time for RTA laser radiation has been calculated to be 20 minutes based on the assumption that the human eye is correctly positioned opposite the RTA at the correct distance and is held absolutely stationary.

The RTA was tested and found to be in compliance with the requirements of European Standard EN 50081-1 and EN50082-1, Electromagnetic Compatibility Generic Standards.

Studies were conducted to assess the depth precision, depth resolution, and reproducibility of retinal thickness mapping by the RTA. Depth precision was defined as the sensitivity with which one can establish the depth of a single interface, while depth resolution was defined as the minimal separation that can be detected between two surfaces. The *in vitro* depth precision was calculated to be five to 10 μm and the depth resolution to be 50 μm. Because the Full Width at Half Maximum (FWHM) was also 10 μm in human subjects, the optimal depth precision was determined to be five to 10 μm and the optimal depth resolution to be 50 μm.

Retinal thickness mapping reproducibility was assessed in five human subjects at three visits. Three scans were obtained at each visit, and the retinal thickness values were analyzed. The intra-visit reproducibility (± 12 μm) was based on three scans performed on five subjects in one visit. Single scan inter-visit reproducibility (± 13 μm) was based on one scan per

visit, while the tri-scan inter-visit reproducibility (± 10 μm) was based on the average of three scans at each visit. These results indicated that the RTA provides sufficient resolution and reproducibility for retinal thickness mapping.