K133758

centervue
at the center of vision

APR 23 2014

510(k) Summary in accordance with 21 CFR 807.92(c)

Device Proprietary Name:	CenterVue Macular Integrity Assessment (MAIA™)
Date of submission:	9 December 2013
FDA Product Code 1:	HPT
FDA Regulation Number 1:	21 CFR 886.1605
FDA Classification Name 1:	Perimeter, Automatic, AC-powered
FDA Identification 1:	A perimeter is an AC-powered or manual device intended to determine the extent of the peripheral visual field of a patient. The device projects light on various points of a curved surface, and the patient indicates whether he or she sees the light.
FDA Product Code 2:	HLI
FDA Regulation Number 2:	21 CFR 886.1570
FDA Classification Name 2:	Ophthalmoscope
FDA Identification 2:	An ophthalmoscope is an AC-powered or battery-powered device containing illumination and viewing optics intended to examine the media (cornea, aqueous, lens, and vitreous) and the retina of the eye.
Common or Usual Name:	Automated perimeter/ophthalmoscope
FDA Panel:	Ophthalmology
FDA Classification:	Class II
510(k) Owner:	CENTERVUE S.p.A. via San Marco, 9H 35129 Padova Italy Telephone: +39 049 7396147 Fax: +39 049 7396148 Contact: Giuliano Barbero, Managing Director email: giuliano.barbaro@centervue.com

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Cap. soc.: € 205.440,00 i.v.

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Establishment Registration Number: 3008422902

Indications for Use: The Macular Integrity Assessment (MAIA™) is intended for measuring macular sensitivity, fixation stability and the locus of fixation, as well as providing infrared retinal imaging. It contains a reference database that is a quantitative tool for the comparison of macular sensitivity to a database of known normal subjects.

Device Description:

MAIA™ integrates in one device an automated perimeter and an ophthalmoscope, providing:

- images of the central retina over a field of view of 36° x 36°, acquired under infrared illumination and a confocal imaging set-up;
- recordings of eye movements obtained by "tracking" retinal details in the live retinal video, acquired at 25 fps, providing a measure of a patient's fixation capabilities;
- measurements of differential light sensitivity (or threshold sensitivity) at multiple locations in the macula, obtained as in fundus perimetry by recording a patient's subjective response (see / do not see) to a light stimulus projected at a certain location on the retina;

MAIA™ works with no pupil dilation (non-mydriatic).

MAIA™ integrates a computer for control and data processing and a touch-screen display and it is provided with a power cord and a push-button. MAIA™ works with a dedicated software application running on a custom Linux O.S.

MAIA is composed of:

1. An optical head;
2. A chin-rest and head-rest;
3. A base, including a touch-screen display.

The optical head comprises:

1. An infrared source at 845 nm (SLD)
2. A line-scanning confocal imaging system of the retina. The line, generated by means of an anamorphic lens, is scanned on the retina while the back-reflected light is de-scanned and revealed by a linear CCD sensor;
3. A projection system comprising visible LEDs to generate Goldmann stimuli and background at controlled luminance values;
4. A fixation target in the shape of a red circle (two different dimensions available);
5. An auto-focus system.

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The base of the MAIA includes:

1. A 3-axis robot that moves the optical head;
2. An embedded PC that hosts the control software and related interface ports;
3. The power supply.

Technical/performance specifications:

Fundus imaging:

- Line scanning laser ophthalmoscope
- Field of view: 36° x 36°
- Digital camera resolution: 1024 x 1024 pixel
- Optical resolution on the retina: 25 microns
- Optical source: superluminescent diode at 845 nm
- Imaging speed: 25 fps
- Working distance: 33 mm

Perimetry:

- Field of view for macular perimetry: 30° x 30°
- Tracking speed: 25 Hz
- Stimuli size: Goldmann III
- Background luminance: 4 asb
- Maximum luminance: 1000 asb
- Stimuli dynamic range: 36 dB

Other features:

- Minimum pupil diameter: 2.5 mm
- Focus adjustment range: -15D and +10D (auto-focus)
- Automatic OD/OS recognition

Clinical Performance Testing:

Reference Database:

The MAIA reference database was developed by obtaining threshold sensitivity data from 494 eyes of 270 normal subjects, enrolled at 4 different clinical sites, using the predicate device, MAIA version 4.08. The age range of the measured population was 21-86 (mean 43, std. dev. 15). The default stimuli grid was used for the measurements, corresponding to the central 10° macular area. Furthermore, the following device settings were used:

- Number of stimuli: 61;
- Size of stimulus: Goldmann III;

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- Duration of stimulus: 200 ms;
- Background luminance: 4 asb;
- Maximum luminance: 1000 asb;
- Threshold algorithm: standard 4-2 staircase;
- Measurement scale: 0 to 36 dB;
- Fixation target: central circle of 1° diameter;
- 20° x 20° perimetric field of view.

Precision data:

A precision study was conducted which measured both individual location thresholds (n = 37 per eye) and average threshold over all locations, using the predicate device, MAIA version 4.08. The default 10° stimuli grid was used for the measurements. Three devices were used, each operated by a different operator. The study included 24 subjects, each tested on one eye only: 12 without pathology and 12 with pathology. Each subject/eye was tested 3 times within a session (3 repeated measures for each subject). Subjects were nested within each configuration, that is, each subject appears in one, unique device-operator configuration only. The design was repeated twice: once for healthy eyes and once for eyes with pathologies.

Twelve subjects with normal eyes and 12 subjects with retinal pathologies were enrolled at two different clinical sites based on the following criteria:

- 4 normal subjects and 4 subjects with retinal pathologies enrolled at site 1 and measured with device 1 by operator 1;
- 4 normal subjects (different from above) and 4 subjects with retinal pathologies (different from above) enrolled at site 1 and measured with device 2 by operator 2;
- 4 normal subjects and 4 subjects with retinal pathologies enrolled at site 2 and measured with device 3 by operator 3;
- All measurements were made using a 20° x 20° perimetric field of view.

Within each pathology category, subjects with varying parameters including age and visual acuity were enrolled. For the pathology group, subjects with early and intermediate age-related macular degeneration as well as with mild, moderate, severe and proliferative diabetic retinopathy were enrolled. Diagnosis of retinal pathology was made by a complete eye examination by an ophthalmologist, including dilated funduscopic examination and pertinent history. Subjects met defined inclusion criteria, but none of the exclusion criteria.

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Precision results:

	Normal	Pathology
# subjects	12	12
Overall Mean	29.7 dB	23.5 dB
Overall Standard deviation	1.14 dB	4.23 dB
Repeatability SD*	0.42 dB	0.75 dB
Reproducibility SD**	0.96 dB	0.75 dB

* Estimate of the standard deviation among measurements taken on the same subject using the same operator and device in the same testing session with repositioning.

** Estimate of the standard deviation among measurements taken on the same subject using different operators and devices, including repeatability.

Individual Grid Point Results:

Group/Parameter		Repeatability SD	Reproducibility SD
Normal	Minimum	0.94	1.06
	Median	1.40	1.80
	Maximum	2.43	2.70
Pathology	Minimum	1.33	1.33
	Median	2.36	2.43
	Maximum	3.16	3.24

Predicate device details:

The predicate device for this Special 510(k) is the FDA 510(k)-cleared CenterVue MAIA device, cleared under 510(k) reference K092187 on 27 May 2010, the administrative details of which are:

Device Proprietary Name: CenterVue Macular Integrity Assessment (MAIA™)

FDA Product Code 1: HPT

FDA Regulation Number 1: 21 CFR 886.1605

FDA Classification Name 1: Perimeter, Automatic, AC-powered

FDA Identification 1: A perimeter is an AC-powered or manual device intended to determine the extent of the peripheral visual field of a patient. The device projects light on various points of a curved surface, and the patient indicates whether he or she sees the light.

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FDA Product Code 2:	HLI
FDA Regulation Number 2:	21 CFR 886.1570
FDA Classification Name 2:	Ophthalmoscope
FDA Identification 2:	An ophthalmoscope is an AC-powered or battery-powered device containing illumination and viewing optics intended to examine the media (cornea, aqueous, lens, and vitreous) and the retina of the eye.
Common or Usual Name:	Automated perimeter/ophthalmoscope
FDA Panel:	Ophthalmology
FDA Classification:	Class II
510(k) Owner:	CENTERVUE S.p.A. via San Marco, 9H 35129 Padova Italy
Indications for Use:	The Macular Integrity Assessment (MAIA™) is intended for measuring macular sensitivity, fixation stability and the locus of fixation, as well as providing infrared retinal imaging. It contains a reference database that is a quantitative tool for the comparison of macular sensitivity to a database of known normal subjects.

Comparison with predicate device:

The following aspects are identical between the subject device and the predicate device:

- Indications for Use/Intended Use
- Device description
- Fundamental technology
- Technical/performance specifications

The differences between the subject device and predicate device are in the design of certain components/sub-assemblies as well as additional functions/feature. A number of the design changes were brought about by component obsolescence and other changes were introduced to simplify manufacture.

The additional functions/features of the subject device are summarized as follows:

1. Time Analysis: a new screen that allows to compare consecutive expert tests taken at different times using the "follow-up" mode. It is possible to display differential threshold values as well as

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a time plot of all numerical indices (average threshold, fixation stability and percent reduced thresholds). This analysis does not give a diagnosis or assessment of disease progression.

2. Option to choose among five grids rather than one: Four additional perimetric grids are now available with the Expert Test, in addition to the default one.
3. Option to move the projection grid and to add custom stimuli: it is now possible to manually set the center of the grid selected for the Expert Test, as an alternative to the grid being automatically centered on the PRL. Stimuli at user-specified locations within the projection field can be added to those of the pre-defined grids.
4. New threshold strategies (4-Levels-Fixed and Scotoma Finder): these two new strategies have been introduced to reduce the examination time, as in supra-threshold perimetric tests. Only four or one (respectively) intensities are tested, hence these tests do not measure the actual threshold but rather a supra-threshold response.
5. Enhanced Fixation: when a patient shows difficulties in recognizing the fixation target, this option allows to project a bright, blinking, white stimulus at the center of the field during PRL calculation.

None of these changes were found to raise new questions of safety or effectiveness.

Conclusion:

Based on the information contained within this submission, it is concluded that revised design of MAIA™ is substantially equivalent to the identified predicate device, the original design of MAIA™ cleared under K092187, which is already in interstate commerce within the USA.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

April 23, 2014

CENTERVUE, S.p.A.
Mr. Roger Gray
VP, Quality and Regulatory
DONAWA LIFESCIENCE CONSULTING
Piazza Albania 10
Rome, Italy 00153

Re: K133758
Trade/Device Name: CenterVue Macular Integrity Assessment (MAIA™)
Regulation Number: 21 CFR 886.1570
Regulation Name: Ophthalmoscope
Regulatory Class: Class II
Product Code: HLI, HPT
Dated: March 17, 2014
Received: March 19, 2014

Dear Mr. Gray:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Deborah L. Falls -S

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

Enclosure

Appendix D

Indications for Use Statement

510(k) Number (if known): K133758

Device Name: CenterVue Macular Integrity Assessment (MAIA™)

Indications for Use: The Macular Integrity Assessment (MAIA™) is intended for measuring macular sensitivity, fixation stability and the locus of fixation, as well as providing infrared retinal imaging. It contains a reference database that is a quantitative tool for the comparison of macular sensitivity to a database of known normal subjects.

Prescription Use (Part 21 CFR 801 Subpart D)	☒	AND/OR	Over-The-Counter Use (21 CFR 801 Subpart C)	☐

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Jan C. Callaway -S
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