MAY 2 7 2010

K092187

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510(k) Summary of safety and effectiveness

SUBMITTER INFORMATION

A.	Company name:	CenterVue SpA
B.	Company address:	via Tommaseo 77, 35131, Padova, ITALY
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D.	Contact person:	Giuliano Barbaro Managing Director
E.	Date summary prepared:	4 April 2010

DEVICE IDENTIFICATION

A.	Generic Device Name:	Ophthalmoscope, AC-powered; Automated Perimeter, AC-powered
B.	Trade/proprietary name:	MAIA™, Macular Integrity Assessment
C.	Classification:	Class II
D.	Product Code:	HLI, HPT

DEVICE DESCRIPTION

The MAIA™ is a confocal, line scanning, infrared, ophthalmoscope, combined with a system for visible light projection to obtain perimetric measurements, using "fundus perimetry" (also "microperimetry").

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;
- **recordings of eye movements** obtained by "tracking" retinal details in the live retinal images and providing a quantitative analysis of fixation characteristics;
- **measurements of differential light sensitivity** (or **threshold sensitivity**) at multiple locations in the macula, obtained by recording a patient's subjective response (see / don't see) to a light stimulus projected at a certain location over the retina;
- comparison of measured threshold sensitivity with a **reference database** obtained from normal subjects, indicating whether measured thresholds are above or below certain percentiles.

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.

INDICATIONS FOR USE

The Macular Integrity Assessment (MAIA™) is indicated for measuring macular sensitivity, fixation stability and the locus of fixation, as well as providing infrared retinal imaging. It contains a reference

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database that is a quantitative tool for the comparison of macular sensitivity to a database of known normal subjects.

SUBSTANTIAL EQUIVALENCE

The MAIA™ device is substantially equivalent to the combination of the following predicate devices with regard to intended use, operating principle, function:

Predicate Device	510(k) Holder	510(k) No.	Date cleared
MP-1 MICROPERIMETER	Nidek Technologies Srl	K023719	December 23rd 2002
MP-1 MICROPERIMETER	Nidek Technologies Srl	K061768	September 28th 2006
CIRRUS HD-OCT(*)	Carl Zeiss Meditec Inc.	K063378	January 26th 2007

(*) only with regard to its retinal imaging sub-system

CLINICAL EVALUATION

Clinical data was collected and evaluated to support the indications for use statement for MAIA™ and to demonstrate substantial equivalence to the above predicate devices.

In particular, the reference database was developed by obtaining threshold sensitivity data from 494 eyes of 270 normal subjects, enrolled at 4 different clinical sites. The age range of the measured population was 21-86 (mean 43, std. dev. 15). Subjects were recruited among the clinics' personnel and among the relatives of the clinics' regular patients. The following MAIA perimetric grid and other device settings were used for the measurements:

- Number of stimuli: 61;
- Macular coverage: 10°;
- Size of stimulus: Goldmann III;
- 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.

PRECISION

A precision study was conducted which measured both individual location thresholds (n = 37 per eye) and average threshold over all locations. 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.

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Subject selection criteria

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;

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.

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

CONCLUSION

As described in this 510(k) Summary, all testing deemed necessary was conducted on the MAIA™ to ensure that the device is safe and effective for its intended use when used in accordance with its Instructions for Use.

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

CenterVue SpA
c/o Mr. Giuliano Barbaro
Managing Director
Via Tommaseo 77
Padova, Italy 35131

MAY 27 2010

Re: K092187
Trade/Device Name: Macular Integrity Assessment (MAIA™) Device
Regulation Number: 21 CFR 886.1605
Regulation Name: Perimeter, Automatic, AC-powered
Regulatory Class: Class II
Product Code: HPT, HLI
Dated: April 22, 2010
Received: April 26, 2010

Dear Mr. Barbaro:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Alexander

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

Enclosure

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Indications for use statement

510(k) Number: K092187

Device Name: Macular Integrity Assessment (MAIA™)

Indications for use:

The Macular Integrity Assessment (MAIA™) is indicated 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 ☑ AND/OR Over-The-Counter Use _____

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

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