



Food and Drug Administration  
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June 8, 2016

CenterVue S.p.A  
Mr. Roberto Gabriotti  
QA & RA Manager  
Via San Marco, 9H  
35129 Padova, Italy

Re: K153181  
Trade/Device Name: MAIA  
Regulation Number: 21 CFR 886.1570  
Regulation Name: Ophthalmoscope  
Regulatory Class: Class II  
Product Code: MYC, HPT  
Dated: March 15, 2016  
Received: April 29, 2016

Dear Mr. Gabriotti:

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" (21 CFR 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,

  
Denise L. Hampton -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

510(k) Number (if known) K153181

Device Name MAIA

Indications for Use (Describe)

The Centervue MAIA is intended for:

- measuring macular sensitivity,
- measuring fixation stability and the locus of fixation,
- providing infrared retinal imaging, and
- aiding visual rehabilitation.

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

Type of Use (Select one or both, as applicable)

- Prescription Use (Part 21 CFR 801 Subpart D)  Over-The-Counter Use (21 CFR 801 Subpart C)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

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

|  |   |
|--|---|
| <b>Device Name:</b>                        | CenterVue MAIA  |
| <b>Type of 510(k) submission:</b>          | Traditional   |
| <b>Date of submission:</b>                 | 15 <sup>th</sup> October 2015   |
| <b>Manufacturer:</b>                       | CenterVue SpA<br>Via San Marco 9h<br>35129 Padova - ITALY   |
| <b>510(k) Owner:</b>                       | CenterVue SpA<br>Via San Marco 9h<br>35129 Padova - ITALY   |
| <b>Phone:</b>                              | +39 049 7396 147  |
| <b>Fax:</b>                                | +39 049 7396 148  |
| <b>FDA Registration Number:</b>            | 3008422902  |
| <b>Owner/Operator Number:</b>              | 10032778  |
| <b>510(k) Submitter and Contact:</b>       | Mr. Roberto Gabriotti<br>QA/RA Manager<br>Via San Marco 9H, 35129 Padova - ITALY  |
| <b>Phone:</b>                              | +39 049 7396 147  |
| <b>Fax:</b>                                | +39 049 7396 148  |
| <b>Email:</b>                              | <a href="mailto:roberto.gabriotti@centervue.com">roberto.gabriotti@centervue.com</a>  |
| <b>FDA Product Code:</b>                   | MYC, HPT  |
| <b>FDA Regulation Number:</b>              | 886.1570  |
| <b>FDA Classification Name:</b>            | Ophthalmoscope; Perimeter, Automatic, Ac-powered  |
| <b>Classification Panel:</b>               | Ophthalmic  |
| <b>Common Name:</b>                        | Ophthalmoscope; Perimeter   |
| <b>FDA Classification:</b>                 | Class II  |
| <b>FDA Identification:</b>                 | 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. 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. |
| <b>Indications for Use / Intended Use:</b> | The Centervue MAIA is intended for: <ul style="list-style-type: none"><li>• measuring macular sensitivity,</li><li>• measuring fixation stability and the locus of fixation,</li><li>• providing infrared retinal imaging, and</li><li>• aiding visual rehabilitation.</li></ul>  |



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**

A previous version of the CenterVue MAIA, a device for macular integrity assessment, has been cleared by FDA under K133758 on 23 April 2014. The present submission relates to a revised version of the MAIA device in which the only difference between the subject device and the MAIA device cleared under K133758 is in the software, where a new function called "Fixation Training" (FT) has been introduced to aid visual rehabilitation of patients with unstable fixation. The FT is independent from the functions available in the device cleared under K133758 and it does not interfere or modify the original functions in any way. No other design changes are being introduced by this revision to the MAIA device.

The FT is intended for visual rehabilitation, to help Vision Rehabilitation Specialists train patients with unstable fixation to improve their fixation stability.

A FT session consists of asking the patient to move his/her gaze according to the trainer's instructions and to an audible signal, so to attempt fixation of the internal visual target using a specific retinal area, which is identified by the trainer ahead of the training session. The center of such area is called Fixation Training Target (FTT).

During the FT session, the MAIA retinal tracker continuously determines the position of the fixation point and provides an audible feedback to the patient in the form of pulses of a certain repetition frequency. The number of pulses / sec (i.e. the repetition frequency) is inversely proportional to the distance between the patient's fixation point at that time and the FTT; when such distance falls below one degree, the sound becomes continuous. Optionally, before starting the FT session, operators are able to replace the continuous sound with an MP3 audio file.

The MAIA device interacts with the patient by directing illumination into the patient's eye. The chin-rest and head-rest are the only parts of the device that contact the patient. The chin-rest includes a patient proximity sensor and is motorized for height adjustment. The biocompatibility of the patient-contacting materials, which are the same as used in the previous version of the subject device (K133758) has been established.

The MAIA device operates as a 'stand-alone' device and does not need to interface with other medical devices.

### **Bench tests**

Because no hardware or firmware change or modification was applied, on respect of the device cleared under K133758, the predicate device maintains compliance with the same electrical safety and performance standards that were applied for the version of the device cleared under K133758, these being:

- IEC 60601-1:2005
- IEC 60601-1-2:2007
- ISO 12866:1999
- ISO 15004- 1:2006
- ISO 15004-2:2007



- ISO 14971: 2007
- ISO 62304: 2006

The same test reports submitted for the MAIA device cleared under K133758 are still valid.

In addition, the Fixation Training software meets the requirements of:

- ISO 62304: 2006
- ISO 14971: 2007

**Identification of predicate devices**

The predicate devices selected for comparison with the subject device are identified as follows:

Primary Predicate Device (PD1): CenterVue MAIA (primary)  
 510(k) Owner: CenterVue  
 510(k) Number: K133758  
 Clearance Date: 23 April 2014  
 FDA Product Code: HPT, HLI  
 FDA Regulation Number: 886.1605, 886.1570  
 FDA Classification Name: Perimeter, Automatic, AC-powered; Ophthalmoscope, AC-powered  
 FDA Classification: Class II

Secondary Predicate Device (PD2): Nidek MP1 (secondary)  
 510(k) Owner: Nidek  
 510(k) Number: K061768  
 Clearance Date: 28 September 2006  
 FDA Product Code: HKI, HPT  
 FDA Regulation Number: 886.1120, 886.1605  
 FDA Classification Name: Perimeter, Automatic, AC-powered; Ophthalmic Camera, AC-powered  
 FDA Classification: Class II

**Predicate Device comparison**

There are no differences in hardware between the subject and primary predicate device.

With regard to software, there are no differences between the subject device and the primary predicate device other than the Fixation Training software, which is not available in the predicate device. With regard to the Fixation Training software and its underlying technological characteristics, there are no substantial differences between the subject device and the secondary predicate device.

Table 1 provides a comparison between the subject device and the predicate devices.

| Table 1 - Predicate device comparison table |                                |                                  |                    |             |
|---|--------------------------------|----------------------------------|--------------------|-------------|
| Item  | Primary predicate device (PD1) | Secondary predicate device (PD2) | Subject device     | Comparison  |
| Device name                                 | MAIA                           | MP1                              | MAIA               | N/A         |
| Device Manufacturer                         | CenterVue                      | Nidek                            | Centervue          | N/A         |
| 510(k) Reference                            | K133758                        | K061768                          | N/A                | N/A         |
| FDA Product Code                            | HPT, HLI                       | HPT, HKI                         | HPT, HLI           | Same as PD1 |
| FDA Regulation Number                       | 886.1605, 886.1570             | 886.1605, 886.1120               | 886.1605, 886.1570 | Same as PD1 |



| <b>Table 1 - Predicate device comparison table</b> |   |  |   |   |
|--|---|--|---|---|
| <b>Item</b>  | <b>Primary predicate device (PD1)</b>   | <b>Secondary predicate device (PD2)</b>  | <b>Subject device</b>   | <b>Comparison</b>                         |
| <b>FDA Classification Name</b>                     | Perimeter, Automatic, AC-powered; Ophthalmoscope, AC-powered  | Perimeter, Automatic, AC-powered; Ophthalmic Camera, AC-powered  | Perimeter, Automatic, AC-powered; Ophthalmoscope, AC-powered  | Same as PD1                               |
| <b>FDA Regulation Number</b>                       | 886.1605, 886.1570  | 886.1605, 886.1120   | 886.1605, 886.1570  | Same as PD1                               |
| <b>Device description</b>                          | Perimeter for macular integrity assessment  | Micro-perimeter for the diagnosis of retinal disease   | Perimeter for macular integrity assessment  | Same as PD1                               |
| <b>Indications for use</b>                         | 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. | The MP-1 is indicated for use as:<br>- Color retinography<br>- Fixation examiner<br>- Fundus-related microperimetry<br>- Visual rehabilitation | The Centervue MAIA is intended for:<br><ul style="list-style-type: none"> <li>measuring macular sensitivity,</li> <li>measuring fixation stability and the locus of fixation,</li> <li>providing infrared retinal imaging, and</li> <li>aiding visual rehabilitation.</li> </ul> It contains a reference database that is a quantitative tool for the comparison of macular sensitivity to a database of known normal subjects. | Similar to PD1, partially the same as PD2 |
| Retinal imaging system                             | Line Scanning Ophthalmoscope  | Fundus camera  | Line Scanning Ophthalmoscope  | Same as PD1                               |
| Background luminance for perimetry                 | 4 asb   | 4 asb  | 4 asb   | Same as PD1 & PD2                         |
| Stimuli size                                       | Goldmann III  | Goldmann I-V   | Goldmann III  | Same as PD1                               |
| Minimum pupil size                                 | 2.5 mm  | 4.0 mm   | 2.5 mm.   | Same as PD1                               |
| Maximum luminance                                  | 1000 asb  | 400 asb  | 1000 asb  | Same as PD1                               |
| Stimuli dynamic range                              | 36 dB   | 20 dB  | 36 dB   | Same as PD1                               |
| <b>Features relevant to the Fixation Training</b>  |   |  |   |   |
| Imaging field                                      | 36° x 36°   | 45° circular (diameter)  | 36° x 36°   | Same as PD1, different from PD2           |
| Imaging and tracking speed                         | 25 Hz   | 25 Hz  | 25 Hz   | Same as PD1 & PD2                         |



| Table 1 - Predicate device comparison table  |  |   |  |                                 |
|--|--|---|--|---------------------------------|
| Item   | Primary predicate device (PD1)                           | Secondary predicate device (PD2)                    | Subject device   | Comparison                      |
| Imaging resolution                           | 1024 x 1024  | 768 x 576   | 1024 x 1024  | Same as PD1, different from PD2 |
| Perimetry field                              | 30° x 30°  | 40° circular (diameter)                             | 30° x 30°  | Same as PD1, different from PD2 |
| Perimetric grids                             | 10° macular, 6° macular, 10-2, customizable within field | Customizable within field                           | 10° macular, 6° macular, 10-2, customizable within field | Same as PD1, equivalent to PD2  |
| Imaging wavelength for eye tracking          | 850 nm   | > 800 nm  | 850 nm   | Same as PD1, equivalent to PD2  |
| Means for identification of the FTT          | Not available  | Manually by eye practitioner using IR retinal image | Manually by eye practitioner using IR retinal image      | Same as PD2                     |
| Fixation stability indices                   | P1, P2 and BCEA  | P1, P2 and BCEA                                     | P1, P2 and BCEA  | Same as PD1 & PD2               |
| Feedback to patient during Fixation Training | Not available  | Repetition frequency of audible pulses              | Repetition frequency of audible pulses                   | Same as PD2                     |

The only differences identified between the predicate devices and the subject device are:

- Indications for use statement
- Imaging and perimetry field
- Imaging resolution

None of these differences introduce new issues of safety and effectiveness. The remaining technical aspects of the devices are identical or very similar.

**Conclusion**

Based on the information contained in this submission, it is concluded that the CenterVue MAIA is substantially equivalent to the identified predicate devices already in interstate commerce within the USA and that any differences that do exist have no effect on the safety and effectiveness of the device.