K100095

Vimetrics, LLC

510(K) Summary

Central Vision Analyzer 1000

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Name of the Device and Classification

Trade Name: Vimetrics Central Vision Analyzer 1000 (CVA-1000)
Regulation Number: 21 CFR 886.1150
Regulation Name: Visual acuity chart
Regulatory Class: Class I
Product Code: HOX

Predicate Device to which Equivalence Is Claimed

Substantial equivalence Is Claimed with the ETDRS, 3 meter, logMAR 0.1, Sloan Letter translucent charts produced in an assortment of contrasts and inserted into an ETDRS standard cabinet with integrated lighting (Precision Vision, La Salle, Ill).

Description of the Device

The CVA-1000 instrument is a standalone device consisting of a computer processing unit with data storage, two LCD monitors, a physician viewed monitor and a patient viewed monitor, and connected keyboard and mouse for physician interaction with a response pad for patient interaction. The instrument provides an evaluation of vision at fixation of one or both eyes under different conditions of contrast and lighting assisting the ophthalmologist or optometrist in evaluating the effects of prescribed refractive instruments such as spectacles or contact lenses and of pharmaceutical treatment or surgical procedures on the central vision of one or both eyes.

The instrument may be used in either of two methods of operation:

Chart Panel: A monitor, viewed by the patient, presents traditional symbol charts with progressive 0.1 logMAR gradations of symbol size, each of which may be presented in the following Michelson contrasts of black letters presented against a white background: 99%, 25%, 20%, 15%, 10%, and 8%

Interactive Central Vision Panel: A monitor is viewed by the patient in which automated measurements are conducted by an interactive computer program at logMAR 0.05 gradations of symbol size.

Similar to measurements conducted in the darkened examining lane with wall charts (predicate device cited above), when testing with the CVA-1000, the patient sits in a chair in the darkened examination room with or without optical correction (spectacles, contact lenses, or trial lenses) and with one eye or both eyes exposed, he/she views in a mirror at the end of the room an LCD monitor (patient monitor) mounted on the wall next to the examiner's desk (total distance entered into the computer program at the time of installation). The examiner, after entering the patient demographic information, selects the method of operation and contrasts to be tested by keyboard and mouse interaction and with information presented on the physician's working monitor.

If the patient has sufficiently poor vision that he cannot identify letters of the largest optotype size when the patient monitor is viewed in the mirror at the specified distance (poorer than 20/320-20/400), the patient monitor may be turned toward the

patient so that it is viewed directly (distance entered into the computer at the time of installation). The examiner selects the desired figure sizes and contrasts to be tested by keyboard and mouse interaction (in this mode the letters are presented in correct orientation without the mirror). Therefore the instrument, in either of the two modes, allows measurement of central vision from 20/10 to 20/1600 depending upon the distance.

Chart Panel:

The examiner may select this method of measuring vision by having the subject view a traditional chart, modeled after the ETDRS, 0.1 logMAR chart. The optotype size steps that are presented on the CVA-1000 patient monitor are the same as those of the 0.1 logMAR ETDRS designed chart, and utilize either Sloane letters, tumbled E's, tumbled Landolt C's, or Lea symbols. Also similar to the 0.1 logMAR reduced contrast ETDRS charts, each optotype size of the CVA-1000 can be tested on a single line and at progressively reduced contrasts from 99% Michelson Contrast to 25%, 20%, 15%, 10%, and 8% (in accord with ANSI specifications). The examiner may view on the physician monitor what is presented to the patient on the patient monitor so he can mark the letters that are correctly identified, allowing either line-by-line or letter-by-letter scoring. The total letters read correctly are recorded as well as the smallest line read correctly in which the traditional method of scoring is utilized (credit is given for a line when 3 or more of the 5 letters are read correctly). The results are saved only when the optical correction is selected for each eye. The charts that are presented utilize a different subset of Sloan letters or symbols for testing the right and left eyes in order to prevent memorization. The monitor viewed by the patient is calibrated at installation using a colorimeter to provide a luminance of at least 200 Cd/'M^2 (in accord with NAS and ANSI specifications) at all times. The gamma of the screen, which determines the black and color contrasts (3600 Kelvin) assures the Michelson Rayleigh contrasts are well within tolerances of +/-1%. Recalibration is required every three months to insure the luminance levels and contrasts presented are correct. During testing the colorimeter automatically monitors and records the room luminance (directed at the wall with the mirror). Because physicians vary in their desire to record chart vision under different lighting conditions, the instrument records but does not restrict the room lighting requirements in this mode of vision measurement.

Once testing is completed, a test results page is presented containing the type of chart used, the contrasts and luminance of the monitor presented as well as the room luminance and type of optical correction. The results page may be printed, and, if the examiner wishes, it may be printed in the language of the patient, among the languages available (currently English and Spanish).

Interactive Central Vision Panel:

In this mode of vision measurement, the CVA-1000 utilizes a Landolt C that is presented on the patient monitor at the center of a large red fixation cross and at each presentation is tumbled in one of 4 positions. At each presentation, the Landolt C is flashed for a duration of 250 msec and is preceded 250 milliseconds by a pedestal of the background representing 3 letter widths in diameter. Following each Landolt C presentation, the patient is allowed up to 4 seconds to decide on the position of the opening of the C presented on the screen and to respond by pushing

one of the 4 buttons placed in a diamond configuration on a response pad that is held by the patient in his lap. As the testing proceeds, the program adapts to the patient's speed of response, speeding up if the responses are quicker and slowing down if the responses are or become slower.

The examination is standardized to test at a room luminance of less than 5 Cd/M^2 illumination, monitored with continuous measurement of the wall surrounding the mirror through which the patient monitor is viewed. Before the testing begins, instructions are first presented on the monitor with video and sound that inform the patient (in the patient language) as to how to respond correctly when each C is presented on the screen. The instructions then conduct a series of test trials with large C's to insure that the patient understands and is following instructions; auditory instructions also encourage the patient throughout the testing. The program then presents C's that progressively enlarge or diminish in size depending upon the responses with a progressively diminishing 6:4:2:1 stepped staircase of 0.05 log MAR steps until a threshold is achieved represented by two correct responses at any one letter size and two negative responses at the next smaller letter size. Once this threshold is reached, the testing of the first "high-contrast" mesopic module is finished.

The computer program then proceeds sequentially, in modular fashion, through a number of additional modules that threshold, in the same manner, the ability of the eye to resolve the orientation of the tumbled Landolt C, but each module presenting a different condition of luminance and contrast. The physician may choose among test panels for those appropriate for the patient and the information he wishes to acquire. It should be noted that every ICVP includes a repeat test of high-contrast letters to evaluate the individual's re-test reliability (reported on the results sheet).

Six **Interactive Central Vision Panels** are currently available (all contrasts are Michelson contrasts)

1. ICVP 3M+3G:

In this panel, the first high-contrast module of white letters presented on a black background is followed by two additional modules of mesopic environmental conditions with lowered contrast, and then 3 modules that simulate glare conditions:99% against 0.5 cd/m^2, 64% against 3 cd/m^2, 43% against 3 cd/m^2, 10% against 200 cd/m^2, 8% against cd/m^2, and 99% against 200 cd/m^2

2. ICVP 2M+1G:

In this panel, the first high-contrast module of white letters presented on a black background is followed by 1 additional module of mesopic environmental conditions with lowered contrast, and then 1 module that simulates glare conditions: 99% against 0.5 cd/m^2, 64% against 3 cd/m^2, 10% against 200 cd/m^2. This test is meant as a shortened form of the ICVP 3M+3G for quick retesting at the physician's discretion on follow-up examinations.,

3. ICVP 6M: (Mesopic contrast panel of 6 tests)

This panel tests acuity in six environments of progressively reduced contrast against a constant mesopic background of 3 cd/m^2. The following Michelson contrasts are tested: 99%, 78%, 64%, 52%, 43%, and 35%.

4. ICVP 3M: (Mesopic contrast panel of 3 tests)
This panel tests acuity in six environments of progressively reduced contrast against a constant mesopic background of 3 cd/m^2: 99%, 64%, 43%. This test is meant as a shortened form of the ICVP 6M for quick retesting at the physician's discretion on follow-up examinations.

5. ICVP 6G: (Glare panel of 6 tests)
This panel tests acuity in six environments of progressively reduced contrast against a constant glare background of 200 Cd/M^2. The following Michelson contrasts are tested 99%, 25%, 20%, 15%, 10%, and 8%.

6. ICVP 3G: (Glare panel of 3 tests)
This panel tests acuity in six environments of progressively reduced contrast against a constant mesopic background of 200 Cd/M^2: 99%, 10%, 8% This test is meant as a shortened form of the ICVP 6G for quick retesting at the physician's discretion on follow-up examinations.

Once testing is completed, a results page is presented with the results for each eye of the threshold acuity for each of the environmental modules. The acuity is presented in the commonly encountered Snellen (i.e. 20/40), together with the contrast level and monitor luminance that was presented and the average room luminance. A picture is also presented for each module that is graphically blurred according to the result obtained and utilizes a Gaussian blur algorithm that was derived from studying a normal population to create a graphic blur that would simulate an equivalent blurred acuity caused by over plus correction with spectacles. A second page is presented that graphically presents comparison with prior measurements of the same eye with similar type of correction and under the same presentation luminance and contrast conditions.

Statement of Intended Use

Indications For Use: The CVA-1000 is intended for use under the direct supervision of an ophthalmologist or optometrist in the measurement of vision at fixation in one or both eyes, with or without optical correction.

Technological Comparisons of the CVA-1000 with the Predicate Device

As stated above, substantial equivalence Is claimed with the ETDRS, 3 meter, logMAR 0.1, Sloan Letter charts produced in an assortment of contrasts and inserted into an ETDRS standard cabinet with back lighting (Precision Vision, La Salle, Ill). In this configuration, the chart presents black letters (or gray letters of the appropriate Michelson contrast) against a white background of 85 to 100 cd/m^2. In the clinical testing that was performed to demonstrate equivalence, for the mesopic modules, charts were purchased with similar contrasts as those presented in the mesopic modules and were reduced in the luminance until the background matched the background of the CVA module. It is recognized that the chart presents a decremental contrast of the letters while the CVA mesopic module presents against the same background luminance an incremental contrast of the presented Landolt C. For the clinical testing of the photopic, glare modules, charts were purchased with the same contrasts, but in this case the background luminances differed, the charts presenting 85 to 100 cd/m^2 from the illuminated cabinet while the CVA-1000

patient monitor presented a background of at least 200 cd/m^2. What was observed from the clinical testing however, was that at these background luminance levels, the Michelson contrast was the important defining variable determining the resultant acuity.

It should be noted that in all cases, the CVA-1000 does not use anti-aliasing in the letter or Landolt C presentation as this has been demonstrated in the smaller letter sizes to influence letter resolution or Landolt C gap opening determination at reduced contrast presentations.

Discussion of the Clinical Studies Performed to Determine Substantial Equivalence with Predicate Device

In 481 eyes of 241 normal individuals, ages 18 to 65, comparisons were evaluated between each of the CVA-1000 modules and an ETDRS letter chart that presented similar Michelson contrast letters (as described above). Testing was performed in emmetropic eyes as well as in eyes with myopia and hyperopia, each tested with contact lens as well as with spectacle correction, in each case with best refraction, totaling 809 comparisons analyzed.

The Pearson correlation coefficients between the vision measured with each module of the CVA and that measured with the corresponding logMAR chart were greater than 0.8 in all but the CVA module that presented 98% black Landolt C's against a bright white background, which was greater than 0.5 but with highly significant correlations ($p<0.001$) demonstrated for all comparisons.

The mean difference between the paired tests performed in the same eye and with the same optical correction remained below 0.1 logMAR, below that of the test-retest reliability of either test indicating that the two tests are essentially similar. The few outliers beyond the 95% confidence limits were spread across all ages. Test-retest differences in logMAR for each of the CVA modules (conducted in 20 individuals, 40 eyes) were similar to that of the ETDRS chart to which it was compared, both nearly zero confirming that with both tests there was no learning effect (minimal influence of the first test score on the latter). In addition, the sigma of the test-retest acuity differences for each of the CVA modules was similar to those of the corresponding chart, also indicating similar reliability

Conclusions Drawn from Clinical Testing with the Device

The clinical studies substantiate the claim that the CVA-1000 is essentially similar to the ETDRS chart that presents a similar luminance and Michelson contrast, demonstrating highly significant Pearson coefficients, similar test-retest reliability sigmas, and differences between the two tests that are similar to the test-retest reliability of each test.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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MAY 10 2010

Re: K100095
Trade Name: Vimetrics™ Central Vision Analyzer-1000 (CVA1000)
Regulation Number: 21 CFR 886.1150
Regulation Name: Visual acuity chart
Regulatory Class: Class I
Product Code: HOX
Dated: March 15, 2010
Received: April 1, 2010

Dear Dr. Sinclair:

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,

for Kesia Alexander

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological and
Ear, Nose and Throat Devices
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Enclosure

Indications for Use

510(k) Number (if known): K100095

Device Name: Central Vision Analyzer 1000 (CVA-1000)

Indications For Use: The CVA-1000 is intended for use under the direct supervision of an ophthalmologist or optometrist in the measurement of vision at fixation in one or both eyes, with or without optical correction.

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

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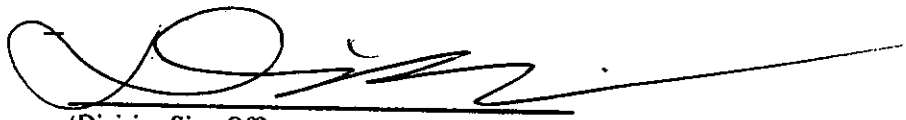
Concurrence of CDRH Office of Device Evaluation (ODE)



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

510(k) Number K100095