K063310

# 510(k) Summary

AUG - 3 2007

seeingmachines

## General Information

| | | |
|---|---|---|
| Device details: | Name Trade: | TrueField Analyzer |
| | Common name: | Visual Field Perimeter |
| | Classification name: | Perimeter, Automatic, AC-Powered |
| | Regulation number: | 886.1605 |
| | Product code: | HPT |
| | Classification panel: | Ophthalmic |
| | Classification: | Class I device |


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Contact person: Dr. Nick Cerneaz, Chief Executive Officer


Date summary prepared: 31 July 2007

## Intended Use

The TrueField Analyzer is an automated perimeter used to aid in measurement of visual field abnormalities.

## Predicate Device Information:

The device has been compared to the following legally marketed devices:

| Company | Device | 510(k) |
|---|---|---|
| Carl Zeiss, Inc | Humphrey Field Analyser (HFA-II) | K954167 |

## Device Description

The TrueField Analyzer is an automated perimeter that is used to aid in measurement of visual field abnormalities. It is an objective device that monitors involuntary responses in the patient's pupils to a series of multi-focal visual stimuli presented to the eyes. The system presents stimuli and monitors the pupil responses in both eyes independently and concurrently.

The device includes:

- a bilateral image display system for providing individual visual stimulus to the patient's eyes (both eyes are concurrently and independently stimulated)
- A pair of video cameras for monitoring the patient's pupils – again concurrently and independently

- A personal computer equipped to run Windows XP Professional Service Pack 2 operating system.
- The TrueField Software system. The TrueField Software automatically manages the stimulus presentation and video data acquisition, ensuring synchronization between the display and video image acquisition; data analysis, storage and presentation of results for review.

The TrueField Analyzer uses a different fundamental technology to the predicate device. It combines standard multi-focal stimulus and analysis technology (as used in other perimetry devices, for example K003442, K983983) with computerized pupil monitoring (for example K920937) allowing the device to objectively measure the visual field map of a patient. In doing so it is substantially equivalent to the predicate device (K954167).

## Performance Data

The TrueField Analyzer has been designed and tested to establish conformance with the product specifications, including electrical safety, electromagnetic compatibility and infra-red radiation safety.

## Predicate Device Comparison

| | **TrueField Analyzer** | **HFA-II** |
|---|---|---|
| Regulation | 886.1605 | 886.1605 |
| Regulation title | Perimeter | Perimeter |
| Product Code | HPT | HPT |
| Device Class | I | I |
| Manufacturer | Seeing Machines | Carl Zeiss Meditec |
| 510(k) | K063310 | K954167 |
| Intended clinical purpose and use | Visual field examination / to measure visual field defects | Visual field examination / to measure visual field defects |
| Visual system stimulus | Sparse-stimulus multifocal stimulus | Single spot of variable luminance and size |
| Measurement technology | Video camera based pupil measurement | User feedback (button press) |
| Visual function assessment | Regression based multifocal analysis | Threshold or suprathreshold sensitivity to spots |
| Visual field defect assessment | Population sample normal database comparison | Population sample Normal database comparison |
| Stimulus luminance[1] | 290 cd/m$^2$ | 0.025 – 3,183 cd/m$^2$ |
| Background luminance[2] | 10 cd/m$^2$ | 10 cd/m$^2$ |

[1] For ease of comparison with the TrueField Analyzer the HFA-II stimulus luminance is given here in units of candela per square meter (cd/m$^2$). Commonly the units used in relation to the HFA-II are apostilbs, the units differ by a scalar constant and the equivalent range is 0.08 – 10,000 apostilbs.

| | TrueField Analyzer | | HFA-II | |
|---|---|---|---|---|
| Number of stimuli locations | # | Test Pattern | # | Test Pattern |
| | 24 | T30-24 | 54 | Central 24-2 |
| | 40 | T30-40 | 76 | Central 30-2 |
| | 60 | T30-60 | 68 | Central 10-2 |
| | 24 | T10-24 | 68 | Peripheral 30/60-2 |
| | 44 | O30-44 | | |
| Eccentricity limits of standard test area | ±30 degrees | | ±24 degrees[3] | |
| Stimulus spot size | 4, 11 or 14 degrees arc angle[4] | | 0.43 degrees[5] | |
| Stimulus spot spacing | ~7.5 to 12.5 degrees[6] | | Uniform 6° grid spacing[7] | |
| Proportion of visual field test area sampled | 88% | | < 0.5% [8] | |
| Total test time | 4 to 5 minutes for both eyes | | 5 to 15+ minutes per eye[9] | |

[2] Again for convenience of comparison the HFA-II background luminance is given in cd/m$^2$ – normally the HFA-II background luminance is specified in apostilbs (31.5 apostilbs = 10 cd/m$^2$).

[3] The HFA-II includes a variety of test patterns at various eccentricity limits, such as 10, 24, 30 and 60 degrees as governed by the various test protocols of that device. Despite those options the *vast* majority of standard testing on the HFA-II is done with the Central 24-2 test pattern, which has a visual field range of ±24° (degrees). Furthermore when the Central 30-2 test is used, only the inner points matching the Central 24-2 test patterns are used to calculate the Pattern Deviations. For these reasons the HFA-II eccentricity limits for the standard test area are noted here as ±24°.

[4] For the T30-24 test. Note that the TFA stimulus is not a circular spot, rather each region is a segment of the total visual field under investigation, and is scaled to account for the hill of vision. The inner ring of the T30-24 stimulus subtends an annulus from 1° to 5° eccentricity, the second ring from 5° to 16° and the third from 16° to 30°. Each annulus is partitioned into 4, 8 and 12 segments respectively, evenly spaced and bounded on the horizontal and vertical meridians thus preserving the quadrants and hemifields of the visual fields. For the T30-24 test pattern the polar angles of the regions in the inner, middle and outer annulus are 90, 45 and 30 degrees respectively giving broadly proportionally sized regions.

[5] Goldmann standard size III spot. This is the default spot size used by the HFA unless it is explicitly overridden by the operator. The vast majority of HFA-II tests are conducted with a size III spot.

[6] For the T30-24 test. As per the description in footnote 4 above the TrueField Analyzer stimulus test pattern is cortically scaled and spaced to ensure complete coverage of the visual field test area excluding the central fixation disk (subtending the central 1° region).

[7] For the standard test patterns (such as 24-2) It is possible to achieve a 4.2° spacing using the HFA-II central 24-2 *and* the 24-1 test patterns (that is conduct two tests per eye) and then merge the results using features of the HFA software. In practice this is an extremely rare event as it more than doubles the required test time.

[8] For the standard central 24-2 test pattern which uses 54 spots each subtending 0.43° of arc (using the standard Goldmann size III stimulus) over the visual field test area eccentricity limits of ±24°, that gives a total coverage = $54 \times \tan^2(0.43/2) / \tan^2(24) = 0.003836 = 0.38\%$. For the central 30-2 test pattern (76 spots each of 0.43° arc over the ±30° of the field) the coverage is = $76 \times \tan^2(0.43/2) / \tan^2(30) = 0.32\%$. In the case of the Central 10-2 test pattern (68 spots each of 0.43° arc over the ±10° of the field) the coverage is = $68 \times \tan^2(0.43/2) / \tan^2(10) = 3.1\%$

[9] A series of tests on the HFA-II 750 perimeter using the central 30-2 test pattern (most comparable to the TrueField Analyzer T30-24 pattern in terms of field limits of ±30°) report average test durations to be approximately: SITA Fast 5 minutes, Fastpac 9.4 minutes and Full Threshold 14.6 minutes per eye. (Bengtsson B, *et al.* 1988 *Acta Ophthalmol. Scand.* **76**:431-7).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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AUG - 3 2007

Re: K063310
Trade/Device Name: TrueField Analyzer™
Regulation Number: 21 CFR 886.1605
Regulation Name: Perimeter, Automatic, AC-Powered
Regulatory Class: I
Product Code: HPT
Dated: July 18, 2007
Received: July 20, 2007

Dear Mr. Donald:

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.

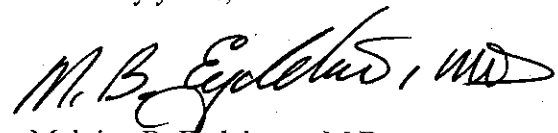
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Malvina B. Eydelman, M.D.
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Enclosure

# Indications for Use Statement

510(k) Number: K063310

Device Name: TrueField Analyzer

Indications For Use:

For the assessment of visual field abnormalities.

Prescription Use ✓ AND/OR Over-The-Counter Use

(21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Marsha L. Burke Nicholas

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

510(k) Number K063310