



Food and Drug Administration  
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August 11, 2016

Ober Consulting Sp. Z.o.o.  
Mr. Jan Krzysztof Ober  
Brzechwy 6, 60-195 Poznan  
Poland

Re: K152890

Trade/Device Name: Saccadometer Plus and  
Saccadometer Advanced

Regulation Number: 21 CFR 886.1510

Regulation Name: Eye Movement Monitor

Regulatory Class: Class II

Product Code: HLL

Dated: July 8, 2016

Received: July 11, 2016

Dear Mr. Ober:

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,

*Kesia Alexander*

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

## Indications for Use

510(k) Number (if known)  
K152890

Device Name

Trade / family name: Saccadometer  
model name: Plus, Advanced

Indications for Use (Describe)

Measuring temporal characteristics of saccadic refixation responses when viewing lateral visual stimulus and identifying the individual time delays of moving the eyes toward the stimuli.

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)

### CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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## 510(k) Summary

06 July 2016

### I. SUBMITTER

Submitter's contact:

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### II. DEVICE

There is no prior submission for the device.

The assigned 510(k) number is K152890/S001.

Proprietary name: Saccadometer Plus, Saccadometer Advanced

Common or usual name: Saccadometer

Classification name: EYE MOVEMENT MONITOR (21 CFR 886.1510)

Classification code: HLL

### III. PREDICATE DEVICE

Permobil Meditech, Ober2, K902954

### VI. DEVICE DESCRIPTION

The Saccadometer system measures eye movements in horizontal axis with temporal 1kHz and spatial resolution < 5 arc min. The system incorporates a built in visual target presentation using miniature laser projectors mounted on the sensor forehead plate. Saccadometer Plus is equipped with three red laser projectors with 10° separation. Saccadometer Advanced has additional extra green laser and it allows to perform more complex saccadic task.

Information about eye movement is acquired by analyzing the infrared light reflected from eye orbit. The left and right eye orbit are illuminated by two infrared LEDs, providing eye surface irradiance below 1mW/cm<sup>2</sup> (operating condition). Due to the conjugacy and synchronicity of the saccadic eye movements, the rotation of left and right eyes, can be added and averaged. The

inner canthi of the left and right eyes are illuminated with the low intensity IR. The difference between the amounts of IR reflected back from the eye surfaces toward the photodetecting circuitry, carries the information about the eye position changes. The eye landmarks are taking part in generation of the eye movement signal. The corneal bulge and the limbus (the border between darker iris and white sclera). Main contributor to the eye movement signal is the corneal bulge. Being the relative eye position measurement system, it requires to define the initial eye position. It means that at the beginning of every measurement, a steady eye fixation point needs to be provided. In Saccadometer the central fixation target serves this purpose.

The Saccadometer Plus and Saccadometer Advanced systems are composed of:

- proprietary hardware and firmware, enclosed in
- examination control unit with 2 x 1.5V AA batteries, and the
- eye movement sensor with integrated miniature laser spot projectors
- proprietary software application LatencyMeter.
- optical fiber to USB data transmitter

Saccadometer's control unit is made of ABS material and it is not used by the tested subject.

Saccadometer uses only three materials that have direct contact with head skin:

- a) Elastic tape with OEKO-TEX 100 certificate
- b) Silicone nose pads
- c) Ring made from M90 acetal (POM) homopolymer plastic
- d) Flex flat cable – insulation material: polyvinyl chloride (PVC)

Saccadometers are supplied in a plastic non sterile boxes filled with a sponge for mechanical safety.

Saccadometer is non sterile device and cannot be sterilized with high temperature processes.

The device is worn on head so it have direct contact with the skin, hairs and sweat. The proper method for cleaning Saccadometer surfaces (having contact with skin) is the disinfection with the use of cotton wipe moistured with ethyl alcohol.

Saccadometer Plus and Saccadometer Advanced is Rx only device. Manual includes the information that the device is for prescription only. The label with the statement (Rx Only) is placed on control unit of Saccadometer (small label) as well as the on plastic box in which Saccadometer is supplied (large label). Device is also labeled by Laser warning label (placed on sensor), Laser class label (sensor), Serial number label (control unit, box), Laser details label on control unit and box, Battery label (control unit, box).

## V. INDICATION FOR USE

### **Indication for use:**

Measuring temporal characteristics of saccadic refixation responses when viewing lateral visual stimulus and identifying the individual time delays of moving the eyes toward the stimuli.

## VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Ober Consulting has determined that the Saccadometer Plus and Saccadometer Advanced is substantially equivalent to the predicate device Permobil Meditech Ober2. The main similarity between Saccadometer Plus/Advanced and Permobil Meditech Ober2 is the same infrared technology used to capture horizontal axis eye movements data with the same high 1kHz sampling rate. The eye movement sensor uses the same material - the PCB board, for carrying the IR illuminators, photodetectors and electronics for signal amplification and IR illumination control.

There are following differences between Saccadometer and Permobil Meditech Ober2:

- Ober2 can be used with any external stimuli source,
- Saccadometer Plus/Advanced have its own miniature laser spot projectors providing fixed separation stimuli angle and is specially designed for measuring latency of eyes movements in response to visually stimuli.

Saccadometer Plus/Advanced design provides higher electrical safety standards from its predicate by using low voltage AA batteries (no connection to AC supply) and by using optical fiber isolation from computer's USB port when uploading eye movements data.

## VII. PERFORMANCE DATA

Following performance data were provided in support the substantial equivalence determination.

### **Biocompatibility testing**

Primary component that have direct contact with forehead skin (a) is made from polyamide 86,5% and synthetic rubber 13,5% and have OEKO-TEX 100, that means it is free of harmful substances and meet human-ecological requirements for product with direct skin contact. The other materials include silicone nose pads (b) which have contact with nose bridge skin and flex flat cable made form PVC which can touch ear skin, head skin or hairs.

Saccadometer Plus/Advanced utilizes the materials that were used in Ober2. No new issues of safety or effectiveness are introduced by using Saccadometer device.

### **Electrical safety and electromagnetic compatibility (EMC)**

Electrical safety and EMC testing were conducted on Saccadometer Plus and Saccadometer Advanced. The Saccadometer Plus and Saccadometer Advanced, complies with standard IEC 60601-1. IEC standards for safety and the 60601-1-2:2014 (emission and immunity).

### **Dimension Stability of Saccadometer Enclosure in High Temperature**

Saccadometer housing was exposed to a temperature of 70 deg of 7 hours duration. High temperatures did not significantly change the dimensions of the enclosure

### **Infrared (IR) photoemission analysis**

Saccadometer is using the eye movement measuring technology, based on infrared illumination. For this reason we evaluated the effects of the used radiation (940 nm) on the safety of the person whose eye movement is measured. Our calculations and measurements are based on IEC

62471 standard: “Photobiological safety of lamps and lamp systems”. Both corneal and retinal exposure are at safe level.

### **Lasers safety**

Power of the lasers doesn't exceed the Class II and is verified at the stage of designing and manufacturing..

### **Experimental verification of the saccade detection algorithm**

To verify the correctness of the Saccadometer algorithm for automatic saccade detection and measurement of saccadic latency we developed test environment, allowing to simulate the saccade response with given parameters on the photoelectric converter. Beside the evaluation of the latency measurement error we decided also to assess the impact of changes of pseudosaccade parameters on this error. The results showed that the mean absolute error of saccadic latency measurement is below 2 ms. The influence of parameters of pseudosaccade course (amplitude, rising edge, trigger to slope delay-simulated latency) changes on the latency of measurement error is also below the value 1ms.

### **Measurement linearity testing**

Evaluation of linearity was performed based on the results of 12 subjects aged 22-69. Studies were performed only outside United States. The experiment was performed in the dark room using the head immobilization, visual stimuli was displayed on the LCD screen. Target was displayed randomly in one of 15 possible (0,  $\pm 5$ ,  $\pm 10$ ,  $\pm 15$ ,  $\pm 20$ ,  $\pm 25$ ,  $\pm 30$ ,  $\pm 35$ ) horizontal location, subjects were asked to move their gaze following the target displacements.

Results showed that mean averaged maximal linearity error for range  $\pm 15$  degree was 1,4 degree. Linearity error increased with the increase of measurement ranges, however it needs to notice that human fixation is not ideally accurate and it is characterized by the error  $\pm 0,3$  degree.

Moreover it requires to point that experiments implemented on Saccadometer Plus/Advanced, require only  $\pm 10$  degree of measurement range.

### **Spatial resolution of eye movement measurement**

Resolution of measurement was calculated for eye position data of 12 subjects (aged 22-69), which took part in measurement linearity testing. All gathered results were within the declared measurement resolution (5 arcmin or better).

### **Temporal resolution and bandwidth**

The Saccadometer's eye movement measurement bandwidth was measured using optical simulator described in “*Experimental verification of the saccade detection algorithm*”. Simulator's IR emitters were driven by sinusoidal wave of controlled frequency. Amplitude change in digitized signal was observed. According to achieved results Saccadometer's eye movement measurement bandwidth (defined as -3dB amplitude loss) is 0 – 200 Hz. Measurement temporal resolution – digitized signal output rate– is 1000 Hz.

### **Reliability study**

Step task experiment (100 trials) was performed on 17 subjects aged 22-69. Studied performed only outside United States. The same experiment was repeated after 5 minutes break (test and

after 5 minute retest). For every person we calculated (using LatencyMeter software) mean saccadic latency and coefficient of variation (CV) as well as mean saccadic duration for test and retest results. We evaluated test-retest reliability, between-session effect, as well as within-session effects. Evaluation of within-session effect was performed only on the results of first measurement (test). Analysis did not reveal any significant difference between the saccadic parameters measured in the test and retest experiment. Results showed high test-retest reliability and did not differ within the session.

### **Summary**

Results of conducted studies demonstrate that the safety and effectiveness profile of Saccadometer is similar to the predicate device.

## VIII. CONCLUSIONS

Based upon the 510(k) summaries and statements (21 CFR 807) and information provided herein, Ober Consulting conclude that the Saccadometer Plus and Saccadometer Advanced are substantially equivalent to the predicate device under the Federal Food, Drug and Cosmetic Act. Conducted studies revealed that Saccadometer allows the safe and effective measurement of temporal characteristics of saccadic refixation responses.