



Food and Drug Administration
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April 26, 2016

Isen Tech & Trading Company, Ltd.
% Linda Bovard, RAC
President
Bovard Consulting LLC
378 Hardy Avenue
Eugene, Oregon 97404

Re: K152727
Trade/Device Name: Isen-goggles
Regulation Number: 21 CFR 882.1460
Regulation Name: Nystagmograph
Regulatory Class: Class II
Product Code: GWN
Dated: March 22, 2016
Received: March 28, 2016

Dear Ms. Bovard:

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,

William J. Heetderks -A

Digitally signed by William J. Heetderks -A
DN: c=US, o=U.S. Government, ou=HHS,
ou=NIH, ou=People,
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cn=William J. Heetderks -A
Date: 2016.04.26 16:06:09 -04'00'

for

Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K152727

Device Name

ISEN-Goggles

Indications for Use (Describe)

The ISEN-Goggles are used to record and visually display movements of the eyes including nystagmus.

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.

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510(k) SUMMARY

Contact Details

Applicant Name: ISEN Tech & Trading Co., Ltd.
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Contact: Martin Liu, CEO
martin@isen.com.cn

Date Prepared: March 20, 2016

Device Name

Trade Name: ISEN-Goggles

Common Name: IR/Video Eye Movement Viewer/Recorder

Classification Name: 882.1460 Nystagmograph; GWN Nystagmograph

Legally Marketed Predicate Device(s)

510(k) Number	Product Code	Trade Name	Applicant
K972631	GWN	ICS Medical VEMR Video Eye Movement Recorder	ICS Medical Corp.

Device Description

This device consists of patient eye goggles with an adjustable, elastic headband, an LCD display, two green LED lights to provide optional focal points, eight infrared LED lights to provide illumination for the internal cameras, an internal SD-type memory, and buttons to operate the device's function. There is also a micro-USB port to facilitate transfer of data captured and stored in the device's SD-type memory.

The patient eye goggles are an opaque, facially worn device fitted with two small video cameras, and two wavelengths of light emitting diodes (LEDs). One set of lights provides illumination for the cameras. The other allows the user to provide a focus point for the patient, if this is desired. These signals are processed by the image processor that allows for near-simultaneous viewing of the video images from both eyes on the attached LCD screen.

Intended Use/Indications for use

The ISEN-Goggles are used to record and visually display movements of the eyes including nystagmus.

Substantial Equivalence Comparison

The predicate device for this submission is the ICS Medical VEMR Video Eye Movement Recorder (ICS VEMR) from ICS Medical that was cleared under K972631.

Table 5-1 Summary of Similarities and Differences

Category	ISEN-Goggles	ICS VEMR K972631
Goggles fitted with IR sensitive video cameras	Yes	Yes
IR Source	IR LEDs Peak Wavelengths (λ) = 940nm (red)	IR LEDs Peak Wavelength (λ) = 940nm (red)
Lights for visual focus point	Yes – 573nm (green)	No
Light blocking opaque goggles	Yes	Yes
Energy Source	Internal Rechargeable Battery	External Power Supply
Components	Goggles Mask 1 and 2 Battery Charger Rechargeable Li-ion Battery (not supplied but required)	Goggles VCR and Remote Separate 17” Display Monitor
Weight	17.6 oz. (mask plus goggles)	12-15oz – Goggles 9lb 4oz – VCR and Remote 37lb 5oz – 17” Display Monitor <hr/> TOTAL: 47lb 5oz – 47lb 8 oz
Interface to control device	Buttons located on goggle-mounted LCD.	Remote Control
Images Splitter/Power supply interface	Image Splitter not necessary with this technology	Yes
Video Recording Capability	Yes (built-in SD-type memory drive). A micro-USB port is provided to enable data transfer.	Yes (built-in VCR)
Video-Goggle interface	An LCD display is attached to the goggles, allowing for simultaneous display of both eyes from two video cameras within the mask.	An interface that allows for display of both eyes on video monitor and provides the power for the video cameras and the LEDs

Both devices are essentially goggles with internal cameras and LED lights. There are some differences. For example, the ICS VEMR product has only one type of LED that displays red light (940 nm) while the ISEN-Goggles has red (940nm) LEDs for illuminating the image

being recorded and green (573nm) LEDs to provide the option of a focal point for the patient during the test.

Many of the other differences relate to the miniaturization of components since the marketing of the ICS VEMR. The ISEN-Goggles combines many of the separate features of the ICS VEMR into one device instead of three separate devices that work together. This contributes to the reduction in overall weight and size of the system. The ISEN-Goggles weigh only 17.6 oz while the ICS VEMR system weighed 47lb 5oz to 47lb 8oz for the ICS VEMR system. The energy sources are also different.

However, these differences do not affect the substantial equivalence; they are still using the same technological basis to accomplish the same purpose.

Non-clinical Testing

Non-clinical testing for the ISEN-Goggles included electrical safety testing of the Goggles and battery charger to IEC 60601-1, electromagnetic compatibility testing of the Goggles and battery charger to IEC 60601-1-2, lamp safety to IEC 62471, compatibility with FCC regulations per 47 CFR Part 15, battery testing to IEC 62133, and biocompatibility testing to ISO 10993. In addition, hardware and software verification and validation was completed.

Clinical Testing

No clinical testing is included in this 510(k).

Summary

The ISEN-Goggles are substantially equivalent to the ICS VEMR in intended use, device features, and use parameters.