JUN - 6 2012

510(k) Summary

SightSaver™ Visual Stimulator K113785

Applicant		Anschel Technology Inc. David Anschel 1 Wildwood Road Rocky Point, NY 11778
Contact Person	Primary	Dr.Glen Park Sr.Director, Clinical and Regulatory Affairs Target Health Inc. 261 Madison Avenue, 24th Floor New York, NY 10016 Phone: (212) 681-2032 Fax: (212) 682-2105 Gpark@targethealth.com
	Secondary	David Anschel 1 Wildwood Road Rocky Point, NY 11778 Phone: 646-662-7453

Device Name	SightSaver™ Visual Stimulator		
Common/Usual Name	SightSaver™		
Classification Names / Numbers and Code	**21 CFR**	**Classification Name**	**Code**
	882.1890	Evoked response photic stimulator	GWE
Regulatory Class	II		
Prescription Status	Prescription Device		
Device / Classification Panels	Diagnostic Neurological Devices		
Predicate Devices	Cadwell LED Goggles		K831231
	XLTEK LED Visual Stimulator Goggles		K011794
Technology	Embedded LEDs (Light-emitting diodes)		
Description of Device	The SightSaver™ Visual Stimulator is used to expose the eyes to light in order to elicit a physiological response. LEDs inside the device flash light at the eye. The SightSaver™ Visual Stimulator is disposable and made with specifically shaped self-sticking adhesive foam padding which conforms to the periocular region of the patient's face. The SightSaver™ is designed to be connected to a triggering and acquisition system which records, analyzes, or processes the patient's responses. The triggering and acquisition system is not included as part of the 510(k).		

Device Indications for Use	The SightSaver™ is an evoked response photic stimulator that is used to apply a visible light stimulus to a patient's eyes for use in evoked response measurements or for electroencephalogram (EEG) activation. The SightSaver™ Visual Stimulator is designed to be used in hospital and clinical settings by trained medical personnel and is for prescription use only.

Predicate Comparison Summary

Device Name	**The SightSaver™ Visual Stimulator**	**Cadwell LED Goggles**	**XLTek Visual Stimulator Goggles**
K Number	**K113785**	**K831231**	**K011794**
Same Intended Use / Indications for Use	Yes	Yes*	Yes
Utilizes embedded LED technology to flash visible light into the eyes for testing purposes	Yes	Yes	Yes
Controlled by a separate triggering device	Yes	Yes	Yes
Typical use flash repetition rate: 0.5Hz – 1.0Hz	Yes	Yes	Yes
ISO 15004-2 compliant	Yes	No	No

Conclusion

The SightSaver™ Visual Stimulator has been tested to higher safety performance standards compared with the predicate devices but is the same as the predicate devices in:

- Intended use
- Overall design and form factor
- Technological characteristics

The function and technology employed by the SightSaver™ Visual Stimulator is similar and introduces no new questions concerning safety and efficacy. Therefore, the SightSaver™ Visual Stimulator is substantially equivalent.

*While Intended Use is the same, the specific wording of the Indications for Use was not available from the manufacturer of the Cadwell LED Goggles

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Anschel Technology Inc.
c/o Dr. Glen Park
Target Health Inc.
261 Madison Avenue, 24th Floor
New York, NY 10016

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Re: K113785
Trade/Device Name: SightSaver™ Visual Stimulator
Regulation Number: 21 CFR 882.1890
Regulation Name: Evoked response photic stimulator
Regulatory Class: Class II
Product Code: GWE
Dated: June 1, 2012
Received: June 4, 2012

Dear Dr. Park:

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,

Kesia Alexander

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
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): **K113785**

Device Name: **SightSaver™ Visual Stimulator**

Indications for Use:

The SightSaver™ is an evoked response photic stimulator that is used to apply a visible light stimulus to a patient's eyes for use in evoked response measurements or for electroencephalogram (EEG) activation.

The SightSaver™ Visual Stimulator is designed to be used in hospital and clinical settings by trained medical personnel and is for prescription use only.

Prescription Use ____X AND/OR Over-The-Counter Use _____

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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