K062015

510(k) Summary for the
Chronos Vision Eye Tracking Device (C-ETD)

This 510(k) Summary is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92.

1. **General Information**

Submitter:	Chronos Vision Wiesenweg 9 12247 Berlin Germany
Contact Person:	Maureen O'Connell O'Connell Regulatory Consultants, Inc. 5 Timber Lane North Reading, MA 01864 Telephone: 978-207-1245 Fax: 978-207-1246
Summary Preparation Date:	October 12, 2006

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2. **Names**

Device Name:	Chronos Vision Eye Tracking Device (C-ETD)
Classification Name:	Nystagmograph Product Code: GWN

3. **Predicate Devices**

The Chronos Vision Eye Tracking Device (C-ETD) is substantially equivalent to a combination of the following devices: Micromedical Technologies Video Eye Monitor (K964325), SensoMotoric Instruments 2D VOG-Video-Oculography (K972243), Fall Prevention Technologies BalanceBack VNG (K042529), DDAT (UK) DDAT OMT (K050098) and Eye Dynamics House IR/VNG (K925111).

4. **Device Description**

The Chronos Vision Eye Tracking Device (C-ETD) facilitates measurement of three-dimensional eye movements and head movement (rotation and translation). It is a basic instrument for many types of vestibulo-oculomotor and visual research functions.

The Eye Tracking Device will be used in combination with appropriate stimulus generators (rotating or translating devices, visual displays).

5. Indications for Use

The Chronos Vision Eye Tracking Device (C-ETD) is intended to provide information to assist in the diagnosis of vestibular disorders by measuring, recording, storing, displaying, and analyzing nystagmus of the eye. The C-ETD is intended for use by qualified medical personnel trained in the use of nystagmographs. This device provides no diagnoses nor does it provide diagnostic recommendations.

6. Performance Data

Testing was provided which verified system performance using an artificial eye model.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

O'Connell Regulatory Consultants, Inc
% Ms. Maureen O'Connell
Regulatory Consultant
5 Timber Lane
North Reading, Massachusetts 01864

OCT 3 1 2006

Re: K062015
Trade/Device Name: Chronos Vision Eye Tracking Device (C-ETD)
Regulation Number: 21 CFR 882.1460
Regulation Name: Nystagmograph
Regulatory Class: Class II
Product Code: GWN
Dated: October 12, 2006
Received: October 13, 2006

Dear Ms. O'Connell:

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 Office of Compliance at (240) 276-0120 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K062015

Device Name: Chronos Vision Eye Tracking Device (C-ETD)

Indications for Use:

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___ ____ (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General,
and Neurological De

510(k) Number K062015