DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 3 1999

Mr. Douglas R. Morr
Chief Engineer
Bertec Corp.
6185 Huntley Road, Suite B
Worthington, Ohio 43229

Re: K991642
Trade Name: EyeTrak™: ENG System
Regulatory Class: II
Product Code: GWN
Dated: May 12, 1999
Received: May 13, 1999

Dear Mr. Morr:

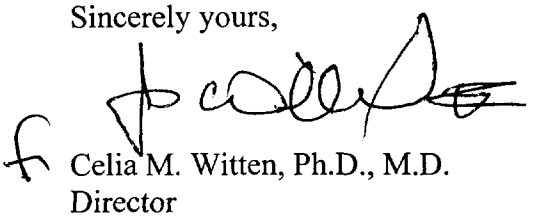
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

BERTEC CORPORATION

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XIV. Statement of Indications for Use:

Statement of Indications for Use

510(k) Number (if known): K991642

Device Name: EyeTrak™ : ENG System

Indications for Use:

The EyeTrak™ is used to non-invasively measure the vertical and horizontal eye movements during a variety of tests performed during electronystagmography (ENG) testing. This testing includes, but is not limited to: saccadic test, smooth pursuit, optokinetic nystagmus, and kinetic vestibular tests. It provides a trained clinician with data and graphs representing a patient's ability to perform certain eye movements voluntarily, as well as the patient's involuntary eye movements due to head movement, eye movement and/or body movement as is normally performed in vestibular diagnostic testing such as in Hallpike positional tests. It is used, then, to aide in the detection and diagnosis of vestibular disorders.

The EyeTrak™ does not incorporate a camera for vertical and horizontal eye movement measurement, therefore it is not as cumbersome as other similar devices, and does not have focal length and resolution limitations based on the camera and camera lens used. The EyeTrak™ instead measures horizontal and vertical eye movement non-invasively using infra-red sensors and an IR oculography method with background light suppression. This allows for direct transmission of sensor signals to a processing unit, which in turn provides the signals to the software for processing, saving, and presentation. A camera and monitor can be used to monitor torsional eye movements, and a sensor can be added to measure head movement.

The results are used to provide documentation of a patient's performance on specific tests.

Prescription Use X
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General Restorative Devices K991642
510(k) Number