October 28,2004

K050098

510(k) SUMMARY

Submitted by: DDAT (UK) Ltd
Camden House
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Kenilworth
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Contact Person: Kevin Eyres, CEO

Date summary prepared: October 28, 2004

Registration Number: 3004059926

Trade Name of Device: DDAT OMT

Common Name: Nystagmograph

Classification Name: Nystagmograph

Product Code: GWN

Regulation number: 21 CFR 882.1460

Device Class Class II

Substantial equivalence: The DDAT OMT is substantially equivalent to the CHARTR® ENG/VNG Diagnostic System marketed by ICS Medical Corporation (File number K991497).

There are no significant differences between the DDAT OMT and the predicate device that would adversely affect the use of the device. The DDAT OMT is substantially equivalent to the predicate device in design, function, materials, and indications for use/intended use.

Description of Device: The DDAT OMT is a computer based medical device comprising of a Computer, a Display Monitor for viewing eye movements, a Lightbar which provides the stimulus for the eye movement and a client amplifier that tracks the patient's eye movement.

Indications For Use: The device is used to observe, record and measure eye movements in patients during ocular motor testing.

The DDAT OMT is intended for use by qualified medical personnel trained in the use of nystagmographs.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 3 2005

DDAT (UK), Ltd.
C/o Ms. Chantel Carson
Underwriters Laboratories Incorporated
333 Pfingsten Road
Northbrook, Illinois 60062

Re: K050098
Trade/Device Name: DDAT OMT
Regulation Number: 21 CFR 882.1460
Regulation Name: Nystagmograph
Regulatory Class: II
Product Code: GWN
Dated: May 16, 2005
Received: May 16, 2005

Dear Ms. Carson:

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) 276-0115 . 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,

for Miriam C. Provost, Ph.D.
Acting Director
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): K050098

Device Name: DDAT OMT

Indications for Use:

The DDAT OMT is intended to be used to observe, record and measure eye movements in patients during ocular motor testing.

The DDAT OMT is intended for use by qualified medical personnel trained in the use of nystagmographs.

Prescription Use ___✓___ (Per 21 CFR 801.109)

OR

Over-The-Counter Use _____ (Per 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 General, Restorative and Neurological Devices

510(k) Number K050098