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AUG 2 5 2003

510(k) Summary
for the
ECLIPSE Systems, Inc.,
Modified Wackers-Liu CQ® Software
(per 21 CFR 807.92)

1. SPONSOR

ECLIPSE Systems, Inc.
540-15 East Main Street
Branford, CT 06405

Contact Person: Mr. William Carroll
Telephone: 203-483-0665

2. DATE PREPARED: August 5, 2003

3. DEVICE NAME

Proprietary Name: Wackers-Liu CQ® Software
Common/Usual Name: ECT Quantitative Analysis and image communication software
Classification Name: Emission Computed Tomography System and Medical Image Digitizer

4. PREDICATE DEVICE

Wackers-Liu CQ® Software (K002229)

5. DEVICE DESCRIPTION

The revised Wackers-Liu CQ® Software is a stand-alone software package. This original product is the automated commercial version of a totally integrated and manually operated cardiac imaging analysis package developed by Drs. Wackers and Liu, and others at the Yale University Cardiovascular Nuclear Imaging Laboratory and described extensively in the peer-reviewed literature. Modifications to the cleared Wackers-Liu CQ® Software consist of changes to the handling of non-circular left ventricular edges and counting voxels. Changes to the Wackers-Liu CQ® Software are transparent to the user.

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6. INTENDED USE

The revised Wackers-Liu CQ® Software is a stand-alone software package for quantification of emission computed tomography (ECT) myocardial perfusion images. The data generated by the Wackers-Liu CQ® Software is intended to be used by the physician in addition to other complementary data in the evaluation of cardiac function and blood supply. It is not meant to replace or eliminate the physician's standard visual interpretation of the patient study or the integration of additional clinical and/or diagnostic information (patient history, stress and/or rest EKG, echocardiogram, etc.) prior to making any final clinical diagnostic or treatment decision. The Wackers-Liu CQ® Software also provides for transmission of ECT images over the internet.

7. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The claim of substantial equivalence is based on indications for use, operational principles, and technological characteristics. A side-by-side comparison of the Wackers-Liu CQ® Software to the cleared Wackers-Liu CQ® Software is provided in Table E-1 below.

Table E-1. Comparison of the Revised and Original Wackers-Liu CQ® Software

Characteristic	Revised ECLIPSE Systems, Inc. Wackers-Liu CQ®	ECLIPSE Systems, Inc. Wackers-Liu CQ® K002229
Used to quantify ECT images	Yes	Yes
Automatic processing	Yes	Yes
Manual processing capability	Yes	Yes
Slice-by-slice viewing	Yes	Yes
3D imaging	Yes	Yes
Computes and displays left ventricular chamber volume	Yes	Yes
Computes and displays ejection fraction	Yes	Yes
Compares data to "normal" database	Yes	Yes
Display left ventricular endocardial/epicardial surfaces	Yes	Yes
Displays polar maps indicating perfusion	Yes	Yes
Displays wall thickening	Yes	Yes
Displays wall motion	Yes	Yes
Displays 3D rendered image of cardiac surfaces	Yes	Yes
Displays short axis, vertical long, and horizontal long slice data	Yes	Yes
Displays single data set or comparison of related data sets	Yes	Yes
Can be executed on most nuclear medical computers	Yes	Yes
Can be executed on PC computers	Yes	Yes
Can be executed on Macintosh computers	No	No

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8. PERFORMANCE TESTING

Verification and validation testing of the revised Wackers-Liu CQ® Software demonstrates that the ECLIPSE Systems, Inc., Wackers-Liu CQ® Software fulfills performance specifications, equivalent to those obtained with the original Wackers-Liu CQ® Software, and correlates favorably with clinical judgment.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 5 2003

ECLIPSE Systems, Inc.
% Ms. Rosina Robison, RN, Med, RAC
Senior Staff Consultant
Medical Device Consultants, Inc.
49 Plain Street
NORTH ATTLEBORO MA 02760

Re: K032500
Trade/Device Name: Wackers-Liu CQ® Software
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: 90 KPS
Dated: August 11, 2003
Received: August 13, 2003

Dear Ms. Robinson:

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 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 one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K032500

Device Name: **ECLIPSE Systems, Inc., Revised Wackers-Liu CQ® Software**

Indications for Use:

The revised Wackers-Liu CQ® Software is a stand-alone software package for quantification of emission computed tomography (ECT) myocardial perfusion images. The data generated by the Wackers-Liu CQ® Software is intended to be used by the physician in addition to other complementary data in the evaluation of cardiac function and blood supply. It is not meant to replace or eliminate the physician's standard visual interpretation of the patient study or the integration of additional clinical and/or diagnostic information (patient history, stress and/or rest EKG, echocardiogram, etc.) prior to making any final clinical diagnostic or treatment decision. The Wackers-Liu CQ® Software also provides for transmission of ECT images over the internet.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Seguin

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K032500

Prescription Use ✓ OR Over-the-Counter Use _____
(Per 21 CFR 801.109)