



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 7 2004

Mr. Elfriede Pagan
RA Specialist
Witt Biomedical Corporation
305 North Drive
MELBOURNE FL 32934

Re: K040195
Trade/Device Name: CALYSTO Image IV – Image and
Information Management System
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and
communication system
Regulatory Class: II
Product Code: 90 LLZ
Dated: January 26, 2004
Received: January 28, 2004

Dear Mr. Pagan:

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.

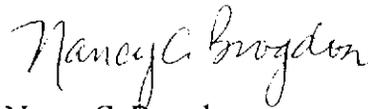
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to 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 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
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K040195

Device Name: CALYSTO Image IV – Image and Information Management System

Indications for Use:

CALYSTO Image IV is an image and information management system intended for image data acquisition, archival, distribution, viewing and analysis for medical images of all modalities as well as Electrocardiogram (ECG) images. It's users, responsible to interpret the data made available, will be professional health care providers. CALYSTO Image IV provides the ability to transmit patient data files for storage, analysis and viewing at distributed locations within the clinical facility via intranet or internet, or may function as a stand-alone device.

The CALYSTO ECG Management System is intended for receiving and storing resting, stress and holter ECG data from source devices. ECG data is stored, unaltered, in its original format, and made available for review and procedural report generation purposes. CALYSTO ECG Management System does not provide interpretive functions, but does store interpretive statements generated by the source device in an integrated and expandable database. Its users, responsible to interpret the data made available, will be professional health care providers. CALYSTO ECG Management System provides the ability to transmit ECG data files for storage, analysis and viewing at distributed locations within the clinical facility via intranet or internet, or may function as a stand-alone device.

Prescription Use _____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 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 Reproductive, Abdominal,
and Radiological Devices
510(k) Number KD40195

Page 1 of 1

(Posted November 13, 2003)