



JUN - 8 2001

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Danish Diagnostic Development A/S
Ms. Pamela K. Gwynn
Engineering Team Leader.
Underwriters Laboratories, Inc.
12 Laboratory Drive
P.O. Box 13995
RESEARCH TRIANGLE PARK NC 27709

Re: K011611
Cardiocam Model 9CSY0799
Dated: May 24, 2001
Received: May 25, 2001
Regulatory Class: II
21 CFR 892.1200/Procode: 90 KPS

Dear Ms. Gwynn:

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 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). 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 requirements, 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) 594-4639. 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 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/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 (s)

B-2 FDA Indications for Use Form

Indications for Use Form

Page 1 of 1

510(k) Number (if known): ~~NOT KNOWN~~ K011611

Device Name: CARDIOCAM

Indications For Use:

The Cardiocam system is a dual head system designed to acquire data for cardiac multi-slice images. The system is intended for use as diagnostic imaging device. When used with appropriate radio pharmaceuticals, images are produced representing the internal distribution of radioactivity in the body. The system allows you to acquire data for high resolution three dimensional, static, gated or dynamic images of biochemical and metabolic processes using Tc-99m, Tl-201, Co-57.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)

David C. Ferguson

Division of
and Radia
510(k) Number K011611