

Pie Medical Imaging B.V.



Pie Medical

JUL 14 1998

Tel.: (+31) 43-3824600
Fax: (+31) 43-3824601

510(k) Summary

CAAS II LVA-Biplane Option

This summary statement complies with 21 CFR, section 807.92(c).

Date summary prepared: 08 June 1998

This premarket notification has been submitted by Pie Medical Imaging B.V. and covers the CAAS II LVA-Biplane option. The address is:

Pie Medical Imaging B.V.
Philipsweg 1
6227 AJ Maastricht
The Netherlands

tel: +31.43.3824600
fax: +31.42.3824601

The contact person is Frank Aniba, Quality Assurance Manager.

The trade name is

CAAS II LVA-Biplane Option.

The common name for this type of device is

Left Ventricular Analysis Software

and the classification name is

Image Processing System (90 LLZ).

The above as stated in 21 CFR, part 892.1570, has been classified as regulatory Class II.

The CAAS II LVA-Biplane Option is substantially equivalent to the Philips CD-Medical CDM 3500 View Station, K945460, and the Philips Integris H/HM family of angiographic imaging systems, K925302, and the Siemens AWOS Angiographic Workstation, K922804.

The CAAS II LVA-Biplane Option is one of the software modules intended to run on the Cardiovascular Angiography Analysis System mark II, CAAS II. It functions in the same manner as other left ventricular analysis software packages. In the End Diastolic (ED) and End Systolic (ES) images (of a monoplane or biplane run), available from various image sources, the outline of the left ventricular contour is either drawn manually or detected automatically. From these contours the ventricular volumes, the ejection fraction and other related parameters are determined using either the Area Length or the Simpson's rule model. Next to the quantification of the ventricular volumes, also the motion of the ventricular wall between ED and ES is quantified from these ventricular contours using four clinically and scientifically established models: the Centerline, Regional, Radial and Slager wall motion models. Finally myocardium dimensions can be estimated from the ED ventricular contour and a manually drawn outline of the epicardium. All results of the analysis are available on screen as well as hardcopy.

The intended use of the CAAS II LVA-Biplane Option is 1) Delineate the outline of the left ventricle automatically on either one (monoplane) or two (biplane) sets of two images of the heart; 2) Absolute measurement of ventricular volumes at the End Diastolic and End Systolic phase of a heart cycle, together with the Ejection Fraction and other to these volumes related parameters; 3) Quantification of the motion of the ventricular wall between the End Diastolic and End Systolic phase of a heart cycle; 4) Estimation of myocardium dimensions.

The CAAS II LVA-Biplane Option is equivalent in technological characteristics to the predicate devices mentioned in this summary:

- The CAAS II LVA-Biplane Option is indicated in the same diagnostic application as the predicate devices.
- The CAAS II LVA-Biplane Option uses, like the predicate devices, only unprocessed and uncompressed images as input to for the analysis.
- The automatic contour detection of the CAAS II LVA-Biplane Option is equivalent to the predicate devices. For the predicate devices manufactured by Philips the automatic contour detection has been shown to generate identical results in tests were the contours were compared on a pixel-by-pixel bases.
- Both monoplane and biplane analysis methods are available in the CAAS II LVA-Biplane Option. Not all of the predicate devices have the biplane method implemented.
- The Area Length and the Simpson's rule volume models are available in the CAAS II LVA-Biplane Option. Not all of the predicate devices have the Simpson's rule model implemented.
- The regression formulas available in the CAAS II LVA-Biplane Option are a combination of those available in the predicate devices and can be found in clinical and scientific literature.
- The Wall Motion analysis models available in the CAAS II LVA-Biplane Option which are based on clinical and scientific literature are a combination of those available in the predicate devices.

The CAAS II LVA-Biplane Option is subject to the same Quality Assurance systems in development and production as other products currently marketed by Pie Medical Imaging.



JUL 14 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850Frank Aniba
Quality Assurance Manager
Pie Medical Equipment B.V.
Philipsweg 1
Maastricht
NetherlandsRe: K982203
CAAS II LVA-Biplane Option
Dated: June 16, 1998
Received: June 22, 1998
Regulatory class: II
21 CFR 892.1600/Procode: 90 IZI

Dear Mr. Aniba:

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 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) 594-4613. 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/dsma/dsmamain.html>".

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION FOR USE STATEMENT

510(k) Number (if known): _____

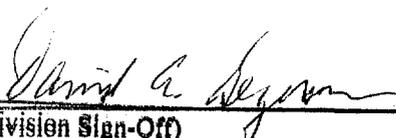
Device Name: CAAS II LVA-Biplane Option

Indications For Use:

Delineate the outline of the left ventricular wall automatically and/or manually in angiographic X-ray images - either monoplane or biplane analysis; Absolute measurements of ventricular volumes - calculation of derived parameters; Quantification of the motion of the ventricular wall by applying several established models - Estimation of the dimensions of the myocardial wall.

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

concurrency of CDRH, Office of device Evaluation (ODE)


Division Sign-Off
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K982203

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____