MAR 17 2004

510(k) Summary **CAAS II RVA**

K033920

This summary statement complies with 21CFR, section 807.92(c).
Date summary prepared: 8 December 2003

This premarket notification has been submitted by Pie Medical Imaging BV and covers the CAAS II RVA software package. Pie Medical Imaging is located at:

Pie Medical Imaging BV
Becanusstraat 13 D 01
6216 BX Maastricht
The Netherlands
tel +31.43.3281328
fax +31.42.3281329
e-mail: carla.devries@pie.nl

The contact person is: Ms. Carla de Vries, Quality Assurance Officer

The trade name is:
CAAS II RVA
The common name for this type of device is:
Right Ventricular Analysis software
and the classification name is:
Image Processing System (LLZ).

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

The CAAS II RVA software package is substantially equivalent to the CAAS II LVA-Biplane Option software package known under FDA number K982203.

The CAAS II RVA 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 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 semi-automatically. From these contours the ventricular volumes, the ejection fraction and other related parameters are determined using several well established volume models for the right ventricle. 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 the well known Centerline model. All results of the analysis are available on screen as well as hardcopy.

The intended use of CAAS II RVA is:

- Delineate the outline of the right ventricular wall semi-automatically or manually on either one (monoplane) or two sets of two angiographic X-ray images of the heart.
- Absolute measurements of right ventricular volumes at the End Diastolic and End Systolic phase of a heart cycle, based on several established models for children and adults, together with the Ejection Fraction and other to these volumes related parameters.
- Quantification of the motion of the right ventricular wall between the End Diastolic and End Systolic phase of a heart cycle.

The CAAS II RVA is substantially equivalent to the predicate device mentioned in this summary by using the same technological characteristics and intended use.

The CAAS II RVA is produced under the same Quality Assurance system applicable to the development and production of products currently marketed by Pie Medical Imaging.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 17 2004

Ms. Carla de Vries
Quality Assurance Officer
Pie Medical Imaging bv
Becanusstraat 13D 01
6216 BX Maastricht
THE NETHERLANDS

Re: K033920
Trade/Device Name: CAAS II RVA
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: December 8, 2003
Received: December 18, 2003

Dear Ms. de Vries:

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

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

Enclosure

510(k) Notification - CAAS II RVA

INDICATION FOR USE STATEMENT

510(k) number (if known): K033920

Device Name: CAAS II RVA

Indications For Use:

Delineate the outline of the right ventricular wall semi-automatically or manually in angiographic X-ray images - either monoplane or biplane analysis; absolute measurements of right ventricular volumes based on several established models for children and adults - calculations of derived parameters; quantification of the motion of the right ventricular wall.

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

concurrence of CDRH, Office of Device Evaluation (ODE)

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

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K033920

(Optional Format 1-2-96)