Pie Medical Imaging
Solutions in Cardiovascular Analysis

K052988

DEC 30 2005

510(k) Summary **CAAS**

This summary statement complies with 21CFR, section 807.92(c).
Date summary prepared: 24 October 2005

This premarket notification has been submitted by Pie Medical Imaging BV and covers the CAAS 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 +31.43.3281329
e-mail: carla.devries@pie.nl

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

The trade name is:
CAAS
The common name for this type of device is:
Cardiovascular Angiography Analysis System
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 software package is substantially equivalent to:
- K945540 CAAS II
- K982203 CAAS II LVA biplane
- K012475 CAAS II QVA
- K033920 CAAS II RVA

CAAS is a new generation of CAAS medical device software that includes and elaborates on previously developed and marketed CAAS software and modules. **CAAS** is designed as a modular software package that includes the functionality of the previously cleared Pie Medical Imaging software. The indications for use remain the same. CAAS consists of reused algorithms with the addition of several improvements that do not influence the indications for use.

CAAS is composed out of six modules CAL, MEAS, QCA, QVA, LVA biplane and RVA.

The intended use of **CAAS** is:
- Quantification of coronary artery dimensions
- Quantification of peripheral arteries and aorta
- Quantification of left and right ventricles
- Management of data resulting of the quantitative analysis

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

The CAAS 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

DEC 30 2005

Caria de Vries
Pie Medical Imaging BV
Becanusstraat 13D
6216 BX Maastricht
The Netherlands

Re: K052988
Trade/Device Name: CAAS (cardiovascular angiographic software)
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: October 18, 2005
Received: October 24, 2005

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 (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 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 this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act 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/industry/support/index.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

INDICATION FOR USE STATEMENT

510(k) number (if known): K052988

Device Name: CAAS

Indications For Use:

CAL
Calculate the pixel size of the image to be analyzed

MEAS
Perform basic length, angle and density measurements.

QCA
Detect the contour of the coronary vessel in the angiographic X-ray image - Generate absolute measurements about the dimensions of the coronary artery segment.

QVA
Detect the contour of the peripheral vessel in the angiographic X-ray image - Generate absolute measurements about the dimensions of the peripheral vessel segment.

LVA biplane
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 left ventricular volumes based on several established models for children and adults - calculations of derived parameters; quantification of the motion of the right ventricular wall.

RVA
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)

David A. Ingram

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices

(Optional Format 1-2-96)