K052023

APPENDIX 6: 510 (K) SUMMARY

DEC 8 2005

510(k) Summary
As required by 807.92
For CADimas™
Prepared on September 27, 2005

Submitted by: Alan Penn & Associates, Inc.
14 Clemson Ct.
Rockville, MD 20850
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Contact Person: Alan Penn, President

Device Trade Name: **CADimas™**

Common Name: Medical Image Processing System

Classification: Class II, Picture Archiving and Communication System Sec. 21 CFR 892.2050

Predicate Device: **CADStream™ Version 4.0** (K043216) and **B-CAD™ System Version 1.0** (K050846) and **3TP Software Option** (K031350).

Manufactured by: Confirma, Inc. 821 Kirkland Avenue Kirkland, WA 98033 ; The Medipattern Corporation 300 Sheppard Ave W Suite 204 Toronto, ON, Canada M9M: 3TP Imaging Sciences 245 Main Street, Suite 620, White Plains, New York 10601.

Description of the Device: **CADimas V1.0™** is a post-processing software package intended for use in viewing and analyzing magnetic resonance imaging (MRI) studies. **CADimas™** supports evaluation of dynamic MRI data acquired during contrast administration. **CADimas™** segments and labels tissue types based on kinetic and margin characteristics of enhancement patterns (parametric image maps), and performs other user-defined post-processing functions (image subtractions, multiplanar reformats).

Intended Use for the Device: **CADimas™ V1.0** is indicated for processing of dynamic contrast enhanced MR images. **CADimas™ V1.0** provides enhanced visualization for image interpretation.

Substantial Equivalence to Predicate Devices: **CADimas™ V1.0** is substantially equivalent to **CADstream™ Version 4.0** and **B-CAD™ System Version 1.0** and **3TP Software Option**. The following is a tabular comparison of the clinically significant features of each.

Device Features	CADimas™ V1.0	Predicate Device CADstream™	Predicate Device B-CAD™	Predicate Device 3TP Software Option
Displays parametric maps	Yes	Yes	No	Yes
Provides viewing and post-acquisition image analysis	Yes	Yes	Yes	Yes
Performs tissue segmentation and classification.	Yes	Yes	Yes	?
Allows the user to interact with the images and overlays	Yes	Yes	Yes	Yes
Allows retrieval of DICOM data from any DICOM-compliant device	Yes	Yes	Yes	?
Designed to assist radiologists to discriminate tissue types.	Yes	Yes	Yes	?
Evaluates Lesion Morphology	Yes	No	Yes	No
Evaluates Lesion Kinetics	Yes	Yes	No	Yes

The intended use, design, and function and performance characteristics for **CADimas™** are substantially equivalent to the predicate devices. It is the opinion of Alan Penn & Associates, Inc. that **CADimas™** raises no new issues of safety and effectiveness as compared to the predicate devices.

Alan Penn & Associates., Inc.
% Mr. Roger H. Schneider
Consultant
Medical & Radiation Technology Consulting
6319 Massachusetts Avenue
BETHESDA MD 20816

Re: K052023
CADimas™ V1.0
Product Code: LLZ
Dated: July 20, 2005
Received: July 26, 2005

Dear Mr. Schneider:

We have reviewed the above referenced premarket notification submission for CADimas™ V1.0, which contains MR contrast agent as a drug component. This drug component is labeled for processing of dynamic contrast enhanced MR images of female breasts. We have discussed the use of this drug component for the indicated use with our Center for Drug Evaluation and Research (CDER) and have been advised that such use constitutes either a new or modified indicated use which has not been found to be safe and/or effective by CDER. Because of this determination, we are unable to complete our review of your section 510(k) notification.

You may resubmit your 510(k) submission after you have received clearance by CDER for the drug component(s) as indicated for use with this device (or when a NDA for the new drug component is expected to be approved within six months) or you may resubmit your 510(k) using (a) different drug component(s) which is (are) approved for the (these) indicated use(s) by CDER.

If the information is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete.

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87, and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Federal Food, Drug, and Cosmetic Act (Act).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 8 2005

Alan Penn & Associates, Inc.
% Mr. Roger H. Schneider
Consultant
Medical & Radiation Technology Consulting
6319 Massachusetts Avenue
BETHESDA MD 20816

Re: K052023
Trade/Device Name: CADimas™ V1.0
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Number: 21 CFR 892.2050
Regulatory Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LNH and LLZ
Dated: November 16, 2005
Received: November 16, 2005

Dear Mr. Schneider:

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

Indications for Use

510(k) Number (if known): K052023

Device Name: **CADimas™ V1.0**

CADimas™ V1.0 is indicated for processing of dynamic contrast enhanced MR images. **CADimas™ V1.0** provides enhanced visualization for image interpretation.

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K052023