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501(k) SUMMARY

SUBMITTERS IDENTIFICATION

Applicant's Name and Street Address:	*IS2 Medical Systems Inc.* *20 Gurdwara Rd., Units 3-10* *Ottawa, Ontario, Canada* *K2E 8B3*
Manufacturing Site:	*IS2 Medical Systems Inc.* *20 Gurdwara Rd., Units 3-10* *Ottawa, Ontario, Canada* *K2E 8B3*
FDA Registration #	*9615403*
Contact Person:	*Victor Woodburn, Manager Quality and Regulatory*
Contact Person E-mail address:	*vwoodburn@is2medical.com*
Telephone and Fax Number of Contact Person:	*T- (613) 228-8755, F – (613) 228-8228*
Date of Submission:	*January 6, 2004*

DEVICE NAME

Device Name (Common):	*Gamma Camera*
Proprietary Name:	*Mobile Compact Digital Cardiac Camera*
Classification Name:	*Emission Computed Tomography System*
Product Code:	*90-KPS*
CFR:	*21CFR 892.1200*
Device Class:	*II*
Predicate Device:	*Compact Digital Cardiac Camera*
(Predicate) 510(k) No.:	*K033199*
Labelling:	*Labels and Instructions for Use can be found in Attachment 1.* *No changes to the labels or Instructions for Use have occurred.*

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INTRODUCTION

This 510(k) Premarket Notification has been prepared to demonstrate that the Mobile Compact Digital Cardiac Camera (MCDCC), manufactured by IS2 Medical Systems Inc., is substantially equivalent to the Compact Digital Cardiac Camera (CDCC), which has previously been through the 510(k) premarket notification process on 510(k) K032779. The mobile system include the mounting of the gantry to the mobile platform incorporating the use of "Dome Mounting" pads to facilitate high load isolation.

INTENDED USE

The intended use of the Mobile Compact Digital Cardiac Camera (MCDCC) is to detect the location and distribution of gamma ray emitting radionuclides in the body and store data for analysis. This device includes accessories such as signal analysis and display equipment, patient and equipment supports, radionuclide anatomical markers, component parts and accessories. The Indications for Use statement can be found in Attachment 2.

DETERMINATION OF SUBSTANTIAL EQUIVALENCE

The intended use of the Mobile Compact Digital Cardiac Camera (MCDCC) is the same range of studies to that of the Compact Digital Cardiac Camera (CDCC) K033199. The detector head is identical in hardware and software. The gantry of the Mobile Compact Digital Cardiac Camera (MCDCC) is optimised for being attached to a mobile platform which is transported from location to location in a truck and has the same range of automatic clinical motions of Compact Digital Cardiac Camera (CDCC) K033199.

The Mobile Compact Digital Cardiac Camera (MCDCC) has been deemed safe and effective and is certified to the same safety standards as the predicate device by a third party organization prior to use on patients. A matrix was constructed comparing the features and intended use of the Mobile Compact Digital Cardiac Camera (MCDCC) with the predicate device. We conclude that the Mobile Compact Digital Cardiac Camera (MCDCC) is substantially equivalent to the predicate device and that no new safety or effectiveness concerns are raised.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 2 2004

Mr. Victor Woodburn
Manager Quality and Regulatory Affairs
IS2 Medical Systems, Inc.
Medical Diagnostic Imaging
20 Gurdwara Road, #3-10
Ottawa, Ontario, K2E 8B3
CANADA

Re: K040057
Trade/Device Name: Mobil Compact Digital Cardiac Camera (MCDCC)
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: 90 KPS
Dated: January 12, 2004
Received: January 14, 2004

Dear Mr. Woodburn:

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) Number (K040057)

Device Name: Mobile Compact Digital Cardiac Camera (MCDCC)

Indications for Use: The intended use of ray emitting radionuclides in the body and store data for analysis. This device resides on a mobile platform and includes accessories such as signal analysis and display equipment, patient the Mobile Compact Digital Cardiac (MCDCC) is to detect the location and distribution of gamma and equipment supports, radionuclide anatomical markers, component parts and accessories.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use Yes (Per 21 CFR 801.109) OR Over-The-Counter Use No

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K040057

(Optional Format 1-2-96)