K033199

501(k) SUMMARY

NOV 1 2 2003

SUBMITTERS IDENTIFICATION

Applicant's Name and Street Address:	*IS2 Medical Systems Inc.* *20 Gurdwara Rd., Units 3-10* *Ottawa, Ontario, Canada* *K2E 8B3*
Contact Person:	*Victor Woodburn, Manager Quality and Regulatory*
Telephone and Fax Number of Contact Person:	*T- (613) 228-8755, F (613) 228-8228*
Address of Manufacturing Site:	*Same as Applicant's Address noted above*
Date of Submission:	*September 30, 2003*

DEVICE NAME

Device Name (Common):	*Gamma Camera*
Proprietary Name:	*Compact Digital Cardiac Camera, (CDCC)*
Classification Name:	Emission Computed Tomography System
Product Code:	90-KPS
CFR:	21CFR 892.1200
Device Class:	II
Predicate Device:	Bi90 Digital Cardiac Camera
510(k) No.: **(Predicate)**	K003882

INTRODUCTION

This 510(k) Premarket Notification has been prepared to demonstrate that the Compact Digital Cardiac Camera, manufactured by IS2 Medical Systems Inc., is substantially equivalent to the Bi90 Digital Cardiac Camera which has previously been through the 510(k) premarket notification process. The COMPACT DIGITAL CARDIAC CAMERA nuclear imaging system has two rectangular fields of view detector heads.

501(k) SUMMARY

INTENDED USE

The intended use of the COMPACT DIGITAL CARDIAC CAMERA 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.

DETERMINATION OF SUBSTANTIAL EQUIVALENCE

The intended use of the COMPACT DIGITAL CARDIAC CAMERA is the same range of studies to that of the Bi90 Digital Cardiac Camera. The detector heads are identical in hardware and software. The gantry of the COMPACT DIGITAL CARDIAC CAMERA is optimized for minimal room space and has the same range of automatic clinical motions of the Bi90 Digital Cardiac Camera.

The COMPACT DIGITAL CARDIAC CAMERA has been deemed safe and effective and is certified to the same electrical 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 COMPACT DIGITAL CARDIAC CAMERA with the predicate device. We conclude that the COMPACT DIGITAL CARDIAC CAMERA 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

NOV 12 2003

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

Re: K033199
Trade/Device Name: Compact Digital Cardiac Camera (CDCC)
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: 90 KPS
Dated: September 30, 2003
Received: October 2, 2003

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

Indications for Use Statement

510(k) Number (K033199)

Device Name *COMPACT DIGITAL CARDIAC CAMERA*

Indications for Use: *The intended use of the COMPACT DIGITAL CARDIAC CAMERA 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.*

To detect or image the distribution of radionuclides in the body or organ using the following technique(s):

	YES	NO	Energy Range (keV)
(a) Planar Imaging	✓		50-250 keV
(b) Whole Body Imaging		✓	
(c) Tomographic Imaging (SPECT) for non Positron emitter	✓		50-250 keV
(d) Positron imaging by coincidence		✓	
(e) Positron imaging without coincidence		✓	
(f) Other indication(s) in the device label, but not included in the above list			None

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological
510(k) Number K033199

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____