PARK SYSTÈMES MÉDICAUX INC. MEDICAL SYSTEMS INC.

K964834

FEB 28 1997

510(K) SUMMARY

1. SUBMITTER IDENTIFICATION

Submitter's Name and Street Address: Park Medical Systems Inc.
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Date of Summary: November 29, 1996

2. DEVICE NAME

Device Name: Gamma Camera

Proprietary Name: ISOCAM II (Dual Head Gamma Camera)

Classification Name: Camera, Scintillation (Gamma)

3. INTRODUCTION

The ISOCAM II is a legally marketed device manufactured by Park Medical Systems Inc.

This 510(K) is being submitted because of a modification to our ISOCAM II, more specifically, an additional collimator for the ISOCAM II, that allows better images. This modification changes the effectiveness of the ISOCAM II, therefore, we are submitting another premarket notification.

The collimator is called MCAT™, which stands for Modular Coded Apperture Technology.

The intended use of the ISOCAM II with MCAT™ is identical to the intended use of the ISOCAM II system we are claiming equivalence to.

4. DETERMINATION OF SUBSTANTIAL EQUIVALENCE

Introduction

The MCAT™ collimator is a position sensitive device that improves the overall effectiveness of the ISOCAM II system. Use of the MCAT™ collimator enables physicians to examine clearer images in which to base their diagnosis.

ISOCAM II with MCAT™ is not going to be marketed for a new or different intended use. Of the criteria referenced in 21 CFR §807.81, para. 3 (i) and 3 (ii), including safety, the only change is effectiveness. The MCAT™ collimator will be added to the list of collimators presently available for use with the system.

Substantial equivalence of ISOCAM II with MCAT™ is being claimed relative to our present ISOCAM II system. A comparison table is given in the following pages.

4. DETERMINATION OF SUBSTANTIAL EQUIVALENCE (Continued)

Comparison Table (Technological Characteristics)

Comparison	*ISOCAM II*	*ISOCAM II with MCAT™*
FDA Status	Class I post amendment device	n/a
Intended Use	The "ISOCAM II" manufactured by Park Medical Systems Inc. is a Single Photon Emission Computed Tomography (SPECT) gamma camera which is intended to image the distribution of radionuclides in the body by means of a single photon radiation detector. This system includes signal analysis and display equipment, patient and equipment supports, radionuclide anatomical markers, component parts, and accessories.	Same as ISOCAM II.
Energy Used/Delivered	There is no new energy source requirement. No energy is delivered or given off. The energy requirement is 220 V, 60 Hz (or 240 V, 50 Hz).	Same as ISOCAM II.
User Instructions	---	No additional instructions are required in the Operator's Manual. Use of the MCAT™ collimator is transparent to the user in all respects, including acquisition set-up and image processing. The MCAT™ collimator will be added to the list of collimators with an ISOCAM II system.
Material Changes	---	There is no addition of materials to the ISOCAM II in order to secure and support the collimator. The weight of the collimator is 200 lbs., which is substantially lower than some collimators presently available for an ISOCAM II system.
Warnings	A warning label is applied to all collimators highlighting instructions.	The same label will be applied to MCAT™ collimator. No changes have been made to the label.

4. DETERMINATION OF SUBSTANTIAL EQUIVALENCE (Continued)

Comparison Table (Technological Characteristics)

Comparison	*ISOCAM II*	*ISOCAM II with MCAT™*
Mechanical Changes	---	There is no mechanical changes to the ISOCAM II to secure and support the MCAT™ collimator. All connection points: collimator to frame, and frame to detector, are identical to the ISOCAM II system. The collimator has been designed to be totally interchangeable with the collimators already available with an ISOCAM II system.
Electrical Changes	---	There is no electrical changes. The electronics that read and identify collimators inserted in the detectors is totally unchanged, in other words, the electronics that presently read the collimators available with an ISOCAM II system is able to read the MCAT™ collimator in the same manner.
Software Changes	---	No software has been added except for some decoding software necessary to decode the initial image data as it appears at the crystal after the photons have passed through the collimator. The decoding software was developed under the same development and change procedures as previously submitted in the ISOCAM II 510(k).
Performance (change in effectiveness)	---	All performance specifications contained in the System Specification are identical to ISOCAM II system with the exception of System Sensitivity and Image Resolution. Better sensitivity and resolution measurements change the effectiveness of the ISOCAM II system.
	System Sensitivity = 190 cpm/μCi/min (with LEHR collimator)	* System Sensitivity ≥ 1000 cpm/μCi/min
	Image Resolution = 3.7-12.3 mm FWHM (0 to 20 cm)	Image Resolution = 5-8 mm FWHM (0 to 20 cm)

5. DETERMINATION OF SUBSTANTIAL EQUIVALENCE - SAFETY

The ISOCAM II with MCAT™ has been deemed by Park Medical Systems Inc. to be safe and effective. With regard to safety, the ISOCAM II has been designed (as a minimum) using the following safety standards:

CAN/CSA-C22.2 No 114-M90
Canadian Standards Association
Diagnostic Imaging and Radiation Therapy Imaging

IEC 601-1
International Electrotechnical Commission
Medical Electrical Equipment - General Requirements for Safety

NEMA XR13
National Electrical Manufactures Association
Mechanical Safety Standard for Power Driven Motions of Electromedical Equipment

NEMA NU 1-1994
National Electrical Manufactures Association
Performance Measurements of Scintillation Cameras

UL544
Underwriters Laboratories Inc.
Standard for Medical and Dental Equipment