



K970128

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510(K) SUMMARY

1. SUBMITTER IDENTIFICATION

Submitter's Name and Street Address: Park Medical Systems Inc.
3195 Louis A. Amos
Lachine, Quebec, Canada
H8T 1C4

Contact Person: Peter Schultz, Manager Quality and Regulatory

Telephone and Fax Numbers of Contact Person: T- (514) 633-9988, F- (514) 633-8674

Date of Summary: January 10, 1997

2. DEVICE NAME

Device Name: 511 KeV Collimator

Proprietary Name: ISOCAM I (Single Head Gamma Camera)
ISOCAM II (Dual Head Gamma Camera)

Classification Name: System, Tomography, Computed, Emission

3. INTRODUCTION

We manufacture single and dual detector gamma cameras, hereafter, called ISOCAM I and ISOCAM II respectively, which recently underwent FDA review.

At the request of the FDA, this 510(K) is being submitted specifically for the 511 KeV collimator option for the Park Medical Systems ISOCAM I and ISOCAM II nuclear imaging systems.

The format for this submission follows the FDA document entitled, "Premarket Notification 510(k) Regulatory Requirements for Medical Devices". In addition to the information in our previous 510(k) which included high energy imaging with 511 KeV collimators, the information requested in the recent FDA letter to industry concerning 511 KeV collimators, has also been included in this submission.

This submission shows substantial equivalence of Park 511 KeV collimators to the pre-amendment high energy collimators used with the Dyna camera.

**4. DETERMINATION OF SUBSTANTIAL EQUIVALENCE -
SAFETY AND EFFECTIVNESS**

The ISOCAM I and ISOCAM II imaging systems have been deemed by Park Medical Systems Inc. to be safe and effective. With regard to safety, they have 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

UL544
Underwriters Laboratories Inc.
Standard for Medical and Dental Equipment

Although no applicable performance standards have been issued under Section 514 of the FD and C Act, the following is the basis for the performance specifications for the 511 KeV collimators for the ISOCAM I and ISOCAM II systems:

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

5. SUBSTANTIAL EQUIVALENCE COMPARISON

Introduction

Based upon the following comparison, Park 511 KeV collimators for the ISOCAM I and II imaging systems have the same characteristics as the predicate device, the Dyna camera 2 series high energy collimators. The comparison table is given in the following pages. The product data sheets for the predicate device are included following the comparison table.

5. SUBSTANTIAL EQUIVALENCE COMPARISON (Continued)

Comparison Table (Technological Characteristics)

<i>Feature/Spec.</i>	<i>Predicate</i>	<i>Park 511 KeV Collimator</i>
Intended Use	The intended use of the Dyna Camera 2 series collimator is to detect and image the distribution of high energy photons from an administered positron emitting radioactive agent in the human body.	Same as predicate.
Physical Description:		
1) Name	High Energy Collimator	Ultra High Energy Collimator
2) No. of holes	1,100 (round)	7,500 (hex)
3) Energy Range	44 - 525 KeV	50 - 562 KeV
4) Thickness	2.5 inches = 63.5 mm	76 mm
5) Hole Size	0.20 inches = 5.08 mm	4 mm
6) Septa thickness	0.156 inches = 3.94 mm	2 mm
7) Field Size	11.8 inches = 300 mm (diameter)	419 mm × 566 mm (rectangular)
Performance	Resolution FWHM = 5.59 mm ^{99m} Tc (surface) = 5.70 mm ¹⁸ F (surface) FWHM = 11.76 mm ^{99m} Tc (3" from surface) = 13.20 mm ¹⁸ F (3" from surface) (3" = 7.62 cm)	Resolution FWHM = N/A ^{99m} Tc (surface) = 5.74 mm (surface) FWHM = 10.1 mm ^{99m} Tc (10 cm from surface) = 11.8 mm ¹⁸ F (10 cm from surface)