

FEB 14 2000

K993960
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**Summary of Safety and Effectiveness
Compliance with 513 (i) of the Federal Food, Drug and Cosmetic Act**

October 2, 1999

1. General Provisions

Common/Usual Name: Radiologic Quality Assurance Instrument

Proprietary Name: Perma-Doc Phantom

Applicant Name and Address:

Mick Radio-Nuclear Instruments, Inc.
1470 Outlook Avenue
Bronx, New York 10465

2. Name of Predicate Devices:

(1)

Manufacturer	K Number
Med Tec, Inc. Iso-Align	Class I exemption under registration A 743531

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Any statement made in conjunction with this submission regarding substantial equivalence to any other product only relates to whether the product can be lawfully marketed without pre-market approval or reclassification and is not to be interpreted as an admission or used as evidence in patent infringement litigation. As the Commissioner of the FDA has indicated, "...a determination of substantial equivalence under the Federal Food, Drug, and Cosmetic Act relates to the fact that the product can be lawfully marketed without pre-market approval or reclassification. This determination is not intended to have any bearing whatsoever on the resolution of patent infringement suits." 42 Fed. Reg. 42,520 et seq. (1977).

3. Classification

This device is classified as a class I device according to 21 CFR 892.1940.

4. Performance Standards

Performance standards for radiologic quality assurance instruments have not been established by the FDA under Section 514 of the Food, Drug and Cosmetic Act.

5. Intended Use and Device Description

In order to ensure the day to day performance of medical devices, many quality assurance tests are performed. In all quality assurance testing a phantom or measurement device is used to either validate a system parameter or measure some aspect of system performance. These test objects/devices can easily be classified as one of two types, passive or active. An active device is one that can make a direct measurement or perform a test without user evaluation or interpretation, while a passive device merely provides an environment or condition for testing, but the result requires the user or operator to make an evaluation and determination. Examples of passive devices are test phantoms or film cassettes.

The Mick Radio-Nuclear Perma-Doc Phantom is an example of a passive device. It is designed to be placed between the source from a HDR system and a piece of film. Radiographic exposure of the film by the HDR source results in the production of an image on the film which can then be analyzed by the operator for consistency from the prior test exposure. The Perma-Doc Phantom does not alter, change or moderate the radiation field in any manner. It has a radio-opaque scale embedded into it that can be visualized on standard x-ray film when exposed to the radiation output from the HDR system. Inspection of the image on the film is then used as part of the quality assurance process.

6. Biocompatibility

No new issues of biocompatibility are raised with regard to this device.

7. Summary of Substantial Equivalence

This device is similar in design and construction, utilizes the identical materials, and has the same intended use and performance characteristics to the predicate devices. No new issues of safety or effectiveness are introduced by using this device.



FEB 14 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850Felix Mick
President
Mick Radio-Nuclear Instruments, Inc.
P.O. Box 99
Bronx, NY 10465Re: K993960
Perma-Doc Phantom
Dated: November 17, 1999
Received: November 22, 1999
Regulatory class: II
21 CFR 892.5050/Procode: 90 IYE

Dear Mr. Mick:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: *To be assigned* K993960

Device Name: Perma-Doc Phantom

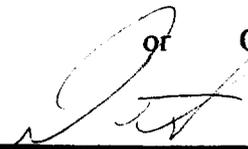
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: or Over-The Counter Use: (Per 21 CFR 801.109)


(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K993960

Perma-Doc 510(k)