K013620

510(k) SUMMARY

[Submitted pursuant to 21 CFR 807.87 (h).]

1. Submitter Information:

Submitter:	Medstone International Incorporated 100 Columbia, Suite 100 Aliso Viejo, California, 92656
Telephone:	(949) 448-7700
Facsimile:	(949) 448-7880
Contact Person:	Ronald H. Bergeson, V.P., Regulatory Affairs
Date Prepared:	October 30, 2001

2. Device:

Trade/ Proprietary Name:	Medstone, Linear Tomography Option
Common/Usual Name:	Linear Tomography Option
Classification Name:	System, X-Ray, Tomographic

3. Predicate Device:

Pausch Corporation Microtom, Tomographic Option

4. Device Description:

The Medstone, Radiographic Linear Tomography Option is designed as an 'add-on' optional device to enable the production of radiologic images of a specific linear cross-sectional plane of the body by blurring or eliminating detail from other planes. A high degree of emphasis for the design of this device was placed on error detection and reliability as well as usability and safety.

5. Device Intended Use:

The Medstone, Radiographic Linear Tomography Option is designed as an optional additional device to the Medstone UroPro 2000 table, intended for use in general radiology. It is designed to enable the production of diagnostic radiologic images of a specific linear cross-sectional plane of the body, eliminating unwanted anatomy and detail by motion blurring of other planes.

This device is designed to provide and control the sweep speed and angle of a

tomography function to enable the production of a properly imaged X-ray film to accomplish diagnostic imaging of a patient.

The table and tomography option are intended to be used by trained professionals, schooled in proper radiology procedures, techniques, positioning and safety.

Device application:

Is the device a life-supporting or life sustaining device?	No
Is the device an implant device?	No
Is the device a sterile device?	No
Is the device for single use?	No
Is the device a diagnostic kit?	No
Is the device for prescription or 'over the counter' (OTC) use?	No
Is the device to be used in the hospital or physician's office?	Yes
Does the device contain a drug or biological product as a component?	No
Does the device design use software?	Yes
Level of concern for software (if applicable)?	Minor
Is the device a diagnostic kit?	No

6. Comparison of Device Technological Characteristics:

PARAMETER	MEDSTONE TOMO OPTION	PAUSCH TOMO OPTION
INPUT/LINE VOLTAGE	110 VAC 1-phase	110 VAC 1-phase
INPUT/LINE FREQUENCY	50/60 Hz	50/60 Hz
TOMOGRAPHIC MOVEMENT	LINEAR	LINEAR
FULCRUM RANGE	0 mm to 250 mm	0 mm to 240 mm
TOMOGRAPHIC ANGLES	20°, 10° and 5°	40°, 30°, 20° and 8°
EXPOSURE TIMES (Controlled by X-Ray Generator)	0.2, to 1.6 secs.	0.4, to 4.0 secs

7. Comparison of Non-Clinical Performance Data:

The assessment of non-clinical performance data as to visual indication of the technique factors, time, angle, layer height and all related safety and effectiveness issues indicates substantial equivalence. The operational performance as to 'sweep time' per degree of 'sweep angle' is within 20% differential and is equivalent with respect to imaging output. This comparison indicates no differences in performance between the Medstone International, Inc. device and the predicate Pausch device.

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8. Comparison of Clinical Performance Data:

It has been concluded that clinical performance data for the Medstone Linear Tomographic, device was not needed for this 510(k) process. The determination of substantial equivalence is, therefore, not based on an assessment of clinical performance for the purpose of this 510(k) process.

9. Conclusions from Non-Clinical and Clinical Tests:

The Medstone International Inc. Linear Tomographic Option perform the same function, in the same environment and have the same intended use as the Pausch Tomographic device.

A comparison of device specifications and principals of operation, indicates that no new questions of efficacy, or substantial risk are raised.

Performance tests of visual indication of the technique factors, time, angle, layer height and all related safety and effectiveness issues indicates complete equivalence between the Medstone International Inc. Linear Tomographic Option and the predicate Pausch Tomographic device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administratio
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 2 2002

Mr. Ronald H. Bergeson
Vice President, Regulatory Affairs
Medstone International, Inc.
100 Columbia, Suite 100
ALISO VIEJO CA 92656

Re: K013620
Trade/Device Name: Medstone, Linear Tomography Option
Regulation Number: 21 CFR 892.1740
Regulation Name: Tomographic x-ray system
Regulatory Class: II
Product Code: 90 IZF
Dated: October 18, 2001
Received: November 5, 2001

Dear Mr. Bergeson:

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 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 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 this 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" (21 CFR Part 807.97). 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

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MEDSTONE INTERNATIONAL, INC.

INDICATIONS FOR USE

510(k) Number: Unknown at this time.

Device Name: Medstone, UroPro 2000, Tomographic Option

Indications for Use:

The Medstone, Radiographic Linear Tomography Option is designed as an optional additional device to the Medstone UroPro 2000 table, intended for use in general radiology. It is designed to enable the production of diagnostic radiologic images of a specific linear cross-sectional plane of the body, eliminating unwanted anatomy and detail by motion blurring of other planes.

This device is designed to provide and control the sweep speed and angle of a tomography function to enable the production of a properly imaged X-ray film to accomplish diagnostic imaging of a patient.

The table and tomography option are intended to be used by trained professionals, schooled in proper radiology procedures, techniques, positioning and safety.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓

OR

Over-The-Counter Use _____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K013627

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