MAY 15 2006

K060870

5. 510(K) SUMMARY

Date Summary Prepared	March 20, 2006
Submitted by	MDS Nordion 447 March Road Ottawa, Ontario K2K 1X8 Canada Tel. (613) 592-3400 Fax. (613) 592-2006
Contact Person	Mr. Ross Kachaniwsky Director, Quality & Regulatory Affairs
Device Name	Avanza
Common Name	Patient Positioning Table
Classification Name	Couch, Radiation Therapy, Powered
Legally Marketed Predicate Device	Precise Treatment Table (K983678)

Description of Device

The Avanza Patient Positioning Table is a powered radiation therapy patient support assembly that is substantially equivalent in functionality and performance as the previously cleared Precise Treatment Table.

The Avanza Patient Positioning Table is supported by a mechanical lift mechanism and features several functions including isocentric rotation, column rotation, longitudinal, lateral, and vertical motions. The computer-controlled table can be activated by using the table mounted control panels or by using an optional hand control.

Intended Use of Device

The Avanza patient positioning table is used as a universal patient support to accurately and reproducibly position patients for radiation therapy and simulation. The Avanza is used with THERATRON® Equinox™ units and is also adaptable to third party radiation therapy treatment devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

MAY 15 2006

Mr. Ross Kachaniwsky
Director, Quality Assurance
MDS Nordion
447 March Road
Ottawa, Ontario, K2K 1X8
CANADA

Re: K060870
Trade/Device Name: Avanza Patient Positioning Table
Regulation Number: 21 CFR 892.5770
Regulation Name: Powered radiation therapy patient support assembly
Regulatory Class: II
Product Code: JAI
Dated: March 23, 2006
Received: March 30, 2006

Dear Mr. Kachaniwsky:

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 (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 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 this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act 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/industry/support/index.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

4. INDICATIONS FOR USE

510(k) Number: K060870

Device Name: Avanza Patient Positioning Table

Indications For Use:

The Avanza patient positioning table is used as a universal patient support to accurately and reproducibly position patients for radiation therapy and simulation. The Avanza is used with THERATRON® Equinox™ units and is also adaptable to third party radiation therapy treatment devices.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K060870