K070574

5. 510(k) Summary as required by 21 CFR 807.92

5.1. Submitter of 510(k)

510(k) owner's name	:	Isodose Control BV
address	:	Landjuweel 11 3905 PE Veenendaal The Netherlands
phone	:	+31 318 502950
fax	:	+31 318 502528
name of contactperson	:	Hub van de Bergh
e-mail	:	hvandebergh@isodosecontrol.com
date the summary was prepared	:	February 20, 2006

APR 13 2007

5.2. Device

5.2.1. Device: Flexitron

name of the device / trade or proprietary name: **Flexitron**
common or usual name: Brachytherapy Afterloader
classification name: Remote controlled radionuclide applicator system
(per 21 CFR section 892.5700 Product code JAQ)

5.2.2. Accessory: Flexisource

name of the device / trade or proprietary name: **Flexisource**
common or usual name: Radioactive Source for Brachytherapy Afterloading
classification name: Radionuclide brachytherapy source
(per 21 CFR section 892.5730 Product code JAQ)

5.2.3. Accessory: Cervix Rotterdam Applicator

name of the device / trade or proprietary name: **Cervix Rotterdam Applicator**
common or usual name: Brachytherapy Applicator
classification name: Remote controlled radionuclide applicator system
(per 21 CFR section 892.5700 Product code JAQ)

5.2.4. Accessory: Vaginal Cylinder Applicator

name of the device / trade or proprietary name: **Vaginal Cylinder Applicator**
common or usual name: Brachytherapy Applicator
classification name: Remote controlled radionuclide applicator system
(per 21 CFR section 892.5700 Product code JAQ)

5.3. Legally Marketed Device(s)

The Flexitron device can be shown to be substantial equivalent to the legally marketed devices cited in the table below.

Device	Manufacturer	510(k) #
microSelectron-HDR Version 2	Nucletron bv	K953946
GammaMed Plus 3/24 High Dose Rate (HDR) Remote Afterloader	Varian Medical Systems Inc	K031524

Isodose Control B.V. ● PO Box 615, 3900 AP Veenendaal ● Landjuweel 11, 3905 PE Veenendaall ● The Netherlands
☎ +31 318 502950 ● 🖷 +31 318 502528 ●@ info@isodosecontrol.com ● KvK: 30191600
www.isodosecontrol.com

5.4. Description of the Device

5.4.1. Flexitron

Flexitron is a computer controlled medical device for brachytherapy treatment.

The Flexitron Remotely Controlled Brachytherapy Afterloading System comprises subjoined listed subsystems:

- TDU - Treatment Delivery Unit
  It houses the radioactive source in its built-in shielding safe, the microcomputer controlled driving mechanism and channel selector mechanism.

- TCC - Treatment Communications Console
  For treatment program data entry, data storage and data displaying.

- TCP - Treatment Control Panel
  It comprises the basic operator elements for start and stop treatment and for displaying device status and used and remaining treatment time.

The TDU houses the shielding safe for storage of the radioactive source and the source drive mechanism for moving the radioactive source into treatment positions within an applicator and back into the safe. There is a channel selector mechanism for selecting one out of 40 treatment channels.
The TDU source drive mechanism and the channel selector mechanism are controlled by microprocessor based electronics. Sensors are applied and their signals are input for the embedded microprocessor for safe and reliable operation. The TDU is connected to mains via a built-in high isolation transformer and an AC/DC power supply converting the mains voltage level to 28 volt for internal machine operation.

The TDU is designed for positioning the source at 401 separate dwell positions in each of the 40 treatment channels and together with dwell time settings for each individual dwell position it enables the creation of isodose shapes targeted to the patients anatomy and geometry in order to irradiate the target patient body site and spare the healthy surrounding tissue.
Dwell positions can be programmed at 1 mm intervals. The maximum source outdrive distance is 1400 mm from the channel selector front plate.
Dwell times are programmable with increments of 0.1 second. Maximum dwell time is 999.9 seconds per position. Minimum dwell time is 0.1 second per position. A dwell position is skipped if its dwell time is 0 seconds.

Before the radioactive source is moved into a treatment channel a check cable is first moved into it. A check cable is of a similar construction of a source cable but without radioactive isotope. It is a measure to check the treatment channel for free passage of the source immediately after the check.

The TDU is connected to TCC via a serial data communications link to receive the patient treatment program and to return data of the performed patient treatment.

TCC allows for manually entering a patient treatment program or for electronically transferring a patient treatment program from Brachytherapy Treatment Planning Software (Treatment planning software is not subject of this 510(k) PreMarket Notification).
During patient treatment TCC displays treatment progress and logs patient treatment data and machine performance data in separate log files.

TDU is connected via another serial communications port to TCP.
TCP is a touchscreen device which is directly controlled from the TDU embedded microprocessor.
TCP allows for starting the patient treatment when all conditions are fulfilled.

Isodose Control B.V. ⁎ PO Box 615, 3900 AP Veenendaal ⁎ Landjuweel 11, 3905 PE Veenendaall ⁎ The Netherlands
☎ +31 318 502950 ⁎ 🖷 +31 318 502528 ⁎@ info@isodosecontrol.com ⁎ KvK: 30191600
www.isodosecontrol.com

5.4.2. Accessory: Flexisource

The Flexisource is the radioactive source for brachytherapy with Flexitron.
A stainless steel capsule accomodates the radioactive isotope Ir-192. This capsule is welded to the outer end of a steel stranded cable. The other end of the stranded cable is connected to the Flexitron built-in cable drive mechanism.

5.4.3. Accessory: Transit tubes and applicators

Transit tubes are guiding the radioactive source to and from the applicator. Transit tubes are connected at one end to the Flexitron device at the channel selector mechanism and at the other end to the body site specific applicator. Applicators are positioned by the physician at the target patient body site.

5.4.4. Other accessories

Other accessories to achieve the utmost performance of the Flexitron device are available to support Brachytherapy Treatment Planning and to support regular hospital QA procedures. Accessories in these categories included with this 510(k) submission are X-Ray Markers and Source Position Check Ruler.

- **X-Ray Markers** are intended to visualize dwell positions in treatment channels and to distinguish the treatment channels on fluoroscopic images to be used for brachytherapy treatment planning.

- **Source Position Check Ruler** is intended to be used for regular check of the source positioning accuracy as part of the hospital regular QA checks.

5.5. Intended use of the Device

The Flexitron Remotely Controlled Brachytherapy Afterloading System is intended to enable an operator to apply by remote control a radionuclide source (Flexisource) into the body or to the surface of the body for radiation therapy.

Flexitron is intended to be used in combination with applicators which makes it suitable for intracavitary, interstitial, intralumenary, bronchial, endovascular, intra-operative and surface brachytherapy treatment.

Flexitron is intended to be used for medical procedures on patients to be prescribed and performerd by a suitably trained and authorized medical professional.

Isodose Control B.V. ⁎ PO Box 615, 3900 AP Veenendaal ⁎ Landjuweel 11, 3905 PE Veenendaall ⁎ The Netherlands
☎ +31 318 502950 ⁎ 🖷 +31 318 502528 ⁎@ info@isodosecontrol.com ⁎ KvK: 30191600
www.isodosecontrol.com

5.6. Technological characteristics of device compared to the predicate device

The Flexitron Remotely Controlled Brachytherapy Afterloading System has similar technological characteristics compared to the legally marketed predicate devices listed above.

All these devices have a subsystem comprising a shielding safe for storage of the radioactive source when not in use, drive mechanism and channel selection mechanism and controlling electronics which is connected to a personal computer for the entry of treatment program data.
All these devices are using a radioactive source sealed in a stainless steel capsule connected to a stranded cable.

The Flexitron device has built-in provisions for operation with two radioactive sources and one check cable. The channel selector mechanism enables the use of check cable and two radioactive sources simultaneously. The device can be configured with two drive mechanisms, one for driving a check cable and one for driving a source cable or it can be configured with three drive mechanisms, one for driving a check cable and two for driving a source cable. The Flexitron device contains an appropriate dimensioned shielding safe and appropriate shielding capability for housing two sources.

This 510(k) PreMarket Notification concerns the configuration with two drive mechanisms, one for driving the check cable and one for driving the source cable.

A variety of applicators dedicated to specific body sites are available with these devices.
In all cases is the therapeutic effect based on the radiation property of the radioactive source.

5.7. Substantial Equivalence

From the discussion in previous paragraphs it can be concluded that the Flexitron Remotely Controlled Brachytherapy Afterloading System has similar technological characteristics compared to the legally marketed predicate devices listed in paragraph 5.2.4.

The differences between Flexitron and predicate devices do not concern the basic principle of operation nor does it adversely effect the safety or effectiveness of the device.

The intended use of Flexitron and predicate devices are the same.

The conclusion is that Flexitron is substantial equivalent to the legally marketed predicate devices.

Isodose Control B.V. ⁕ PO Box 615, 3900 AP Veenendaal ⁕ Landjuweel 11, 3905 PE Veenendaal ⁕ The Netherlands
☎ +31 318 502950 ⁕ 🖷 +31 318 502528 ⁕@ info@isodosecontrol.com ⁕ KvK: 30191600
www.isodosecontrol.com

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Mr. Hub van de Bergh
Quality Assurance & Regulatory Affairs Officer
Isodose Control B.V.
Landjuweel 11
3905 PE Veenendaal
THE NETHERLANDS

APR 13 2007

Re: K070574
Trade/Device Name: Flexitron
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote controlled radio-nuclide applicator system
Regulatory Class: II
Product Code: JAQ
Dated: February 23, 2007
Received: February 28, 2007

Dear Mr. van de Bergh:

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.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 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 (240) 276-3150
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

isodose control®

Indications for Use

510(k) Number (if known): pending K070574

Device Name: Flexitron

Indications for Use:

The Flexitron Remotely Controlled Brachytherapy Afterloading System is intended to enable an operator to apply by remote control a radionuclide source (Flexisource) into the body or to the surface of the body for radiation therapy.

Flexitron is intended to be used in combination with applicators which makes it suitable for intracavitary, interstitial, intralumenary, bronchial, endovascular, intra-operative and surface brachytherapy treatment.

Flexitron is intended to be used for medical procedures on patients to be prescribed and performed by a suitably trained and authorized medical professional.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lyerly

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K070574

Isodose Control B.V. • PO Box 615, 3900 AP Veenendaal • Landjuweel 11, 3905 PE Veenendaall • The Netherlands
☎ +31 318 502950 • 🖷 +31 318 502528 • @ info@isodosecontrol.com • KvK: 30191600
www.isodosecontrol.com