SEP 29 1998

K982446

**AMERICAN BIOPHYSICS, INC.**
**10241 E. Thompson Rd.**
**Indianapolis, IN 46239**

## Non-Confidential Summary of Safety and Effectiveness


July 14, 1998

AMERICAN BIOPHYSICS, INC. Tel - (317) 862-1214
10241 E. Thompson Rd.
Indianapolis, IN 46239

**Official Contact:** Joseph Montebello, M.D. - President

**Proprietary or Trade Name:** Dynamic Shielding Radiation Table

**Common/Usual Name:** Powered radiation therapy patient support assembly

**Classification Name:** Powered Radiation Therapy Patient Support Assembly

**Device:** Dynamic Shielding Radiation Table

**Predicate Devices:** Siemens - ZXT Treatment Table - K910971

**Device Description:**

The Dynamic Radiation Table, is a PC-controlled table which permits total body radiation and incorporates a series of moving tables or trays - one for the patient to lie on, protective organ shields tray and an attenuating tray. It incorporates a number of features such as x-ray trays for verification of radiation dose, number of safety features and limit switches.
Guard is a thin-wall sleeve which when attached to a Filter or Filter / HME housing, is pulled over the breathing

**Intended Use:**

Indicated Use -- To be used in treatment where whole body radiation therapy is indicated. The shielding tray reduces the radiation exposure to those organs, such as lungs, which are desired to be shielded.

Environment of Use -- Hospital

**Comparison to Predicate Devices:**

| Attribute | Dynamic Shielding Table Proposed device | Predicates (See specific listing) |
|---|---|---|
| **Use** | | |
| Intended for a patient to lie on during radiation therapy | Yes | Siemens ZXT K910971 |
| Intended to be used in a hospital | Yes | Siemens ZXT |

| Attribute | Dynamic Shielding Table Proposed device | Predicates (See specific listing) |
|---|---|---|
| **Design** | | |
| Patient lays on table during therapy treatment | Yes | Siemens ZXT |
| Motorized mechanism to move the table in a longitudinal direction | Yes | Siemens ZXT |
| Ability to move in a vertical plane manually | Yes | Siemens ZXT |
| Digital indicators of movement on the operator panel | Yes | Siemens ZXT |
| PC based control of motor | Yes | Siemens ZXT |
| **Safety features** | | |
| Automatic termination of treatment if table fails to move | Yes | Siemens ZXT |
| Automatic termination of treatment if table speed varies more than 5% from programmed speed | Yes | Not available |
| Patient capacity | >500 lbs. | 298 lbs. |
| Incorporate slots below the patient which permit verification of patient placement, shielding, accuracy and dose measurements | Yes | Not done |
| Has Plexiglas housing for holding bolusing materials in place | Yes | Current practice - lay bolusing material over and around patient |
| **Dynamic shielding tray** | | |
| Utilizes custom lead shields | Yes | Current manual practice |
| Shields are placed over patient and aligned by the clinician | Yes | Current practice |
| Maintenance of shields over patients organ | Automatic | Performed manually by technician moving them |
| Tray moves via motorized system traveled coincident to the direction of placement of the patient table | Yes | Predicate is manual |
| **Attenuating Tray** | | |
| Stand which holds lead sheets used to attenuate the beam | Yes | Not available |
| **Attenuating Tray** | | |
| Stand has a safety interconnect which assures that the attenuation stand is in place before the table and beam are activated | Yes | Not available |

| Attribute | Dynamic Shielding Table Proposed device | Predicates (See specific listing) |
|---|---|---|
| **Materials** | | |
| Table is made of steel / aluminum rails | Yes | Siemens ZXT |
| Utilizes low voltage motor system | Yes | Siemens ZXT |
| Plexiglas housing for trays | Yes | Standard for current practice |
| **Performance Standards / Specifications** | | |
| None applicable under Section 514 | Yes | Yes |

**Differences Between Other Legally Marketed Predicate Devices**

The differences in the proposed device and a predicate, Siemens ZXT, are -

1. The proposed device is intended to be used to provide controlled motion of the patients during the radiation therapy treatment while standard radiation therapy couches are intended to provide stationary patient therapy to the designated area.
2. The proposed device range of motion in the longitudinal direction allows the whole patient body to be swept through the beam of radiation from head to toe.
3. Shielding tray is motorized and controlled to move the shields coincident with the motion of the table over the organs to be protected. This method reduces the potential of radiation exposure to the sensitive organs, e.g., lungs, which are intended to be protected.
4. Attenuating stand has a safety interlock to assure that it is in place before beam is activated.
5. The Plexiglas housing on the table permits the patient have bolusing material place around them in a more convenient fashion.

There are no other differences which would have a significant effect of the safety or effectiveness of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 29 1998

American Biophysics, Inc.
c/o Promedic, Inc.
Paul E. Dryden
6329 W. Waterview Court
McCordsville, IN 46055

Re: K982446
Dynamic Shielding Radiation Table
Dated: July 14, 1998
Received: July 15, 1998
Regulatory class: II
21 CFR 892.5770/Procode: 90 JAI

Dear Mr. Dryden:

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 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,

Lillian Yin, Ph.D.
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



Pursuant to the Notice of February 6, 1996 regarding listing of Indications for Use on a separate sheet, the following is per that request.

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

**Device Name:** Dynamic Shielding Radiation Table

**Indicated for Use :** To be used in treatment where whole body radiation therapy is indicated. The shielding tray reduces the radiation exposure to those organs, such as lungs, which are desired to be shielded.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David G Segan

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K982446

**Prescription Use** ✓ or **Over-the-counter use** __
(Per CFR 801.109)