K061638

BEST MEDICAL INTERNATIONAL, INC.

AUG - 4 2006

VII. Summary of Safety and Effectiveness

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807, this is to serve as a Summary of Safety and Effectiveness for the proposed Best Medical International, Best Strand component device.

Manufacturer:

Best Medical International, Inc.
7643 Fullerton Road
Springfield, VA 22153
Phone: (703) 451-2378
Fax: (703) 451-4736.

Contact Person:

Michael J. Phelan
Dir, Quality and Regulatory Affairs

Device Name:

Trade Name:	Best Strand
Common Name:	Brachytherapy Synthetic, Absorbable Placement Sleeve Accessory to seed and spacer components.
Proprietary name:	Best Strand
Classification:	Radionuclide brachytherapy source (accessory to)

Date Prepared: June 8, 2006

Predicate Device: The predicate device to the Best Medical, Best Strand accessory device is the CP Medical CARRIER SLEEVE accessory device (K034062), and the I-125 Rapid Strand's accessory Sleeve (K940632 and K010821).

Device Description: The Best Medical International, Inc, Best Strand consists of synthetic absorbable polymer or copolymer material, braided and non-braided, which is used with absorbable seeding spacers to facilitate the introduction of radionuclide seeds and spacers into the body during Brachytherapy procedures.

Intended Use: Best Medical International's synthetic, absorbable placement sleeve accessory (Best Strand) is intended to be used with absorbable seeding spacers to facilitate the introduction of radionuclide seeds and spacers into the body during

Brachytherapy procedures. It is used to orient, hold, carry and maintain spacing of the radionuclide seeds and the spacer component.

Indications: The Best Medical International, Inc Best Strand component device is indicated for use as an accessory in brachytherapy procedures. It is supplied sterile as a single-use device. The Best Strand is indicated for use in soft tissue or organ tissue but should not be used during cardiovascular or neurological procedures.

Comparison of Technological Characteristics: The proposed device, the Best Strand is comprised of a synthetic absorbable suture material and is intended to facilitate the loading, delivery and implantation of radioactive seeds and spacers. Similarly, the predicate device is composed of synthetic absorbable suture material intended to facilitate the loading, delivery and implantation of radioactive seeds and spacers.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

AUG - 4 2006

Mr. Michael J. Phelan
Best Medical International, Inc.
7643 Fullerton Road
SPRINGFIELD VA 22153

Re: K061638
Trade/Device Name: Best Strand, Best Spacer
Regulation Number: 21 CFR 892.5730
Regulation Name: Radionuclide brachytherapy source
Regulatory Class: II
Product Code: KXK
Dated: June 8, 2006
Received: June 14, 2006

Dear Mr. Phelan:

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

BEST MEDICAL INTERNATIONAL, INC.

Appendix 2

Indications for Use Form

510 (k) Number: K061638

(1) Device Name(s): Best Strand, Best Spacer

Indications For Use:

The Best Medical International, Inc **Best Strand** component device is indicated for use as an accessory in brachytherapy procedures. It is supplied sterile, as a single-use device. The Best Strand is indicated for use in soft tissue or organ tissue but should not be used during cardiovascular or neurological procedures.

The Best Medical International, Inc., **"Best Spacer"** device is intended to be used to maintain a predetermined space between radionuclide seeds during the introduction of the seeds into the body during Brachytherapy procedures. Absorbable spacers are indicated for use in soft tissue or organ tissue but should not be used during cardiovascular or neurological procedures.

(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)

David R. Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K061638

Revised 7/31/2006