K042786

NOV 1 8 2004

BEST MEDICAL INTERNATIONAL, INC.

Attachment to Appendix 1

Summary of Safety and Effectiveness Information

The safety and effectiveness of the BEST Model Nos. 81-01-11, 81-01-14, and 81-01-14 sources will be demonstrated if these sources are substantially equivalent to the BEST Model No. 81-01 source (FDA 510(K) Approval No. K910710), which is addressed in the AAPM's TG 43 document. Air kerma measurements at NIST and TG-43 parameter measurements at the University of Kentucky for the BEST Model No. 81-01-17 intermediate downsize source has shown that it is a pure Ir-192 source, whose dosimetry is in substantial agreement with that of TG-43. The BEST Model Nos. 81-01-11 and 81-01-14 sources have the same pure Ir-192 gamma ray spectrum as that of the BEST Model No. 81-01-17 source. Therefore, for brachytherapy applications, the dosimetry of the three sources (i.e., the BEST Model Nos. 81-01-11, 81-01-14, and 81-01-17) should all be the same, and substantially equivalent to that of the TG-43. Further, BEST has committed that these sources will meet FDA recognized standards.

BEST has filed an amendment to NRC to register these sources under NRC Registration Certificate NR-187-S-101-S. Under the new NRC guidelines, BEST provided testing data to the NRC to demonstrate the safety of these sources. Part of the testing data provided to the NRC demonstrated that these new sources meets FDA recognized standards for Photon-emitting Brachytherapy Sources (i.e., ANSI N43.6-1977 Classification of Sealed Radioactive Sources, and ISO 2919 Sealed radioactive sources – General requirements and classification).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 18 2004

Mr. Sankara I. Ramaswamy
Manager, Regulatory Affairs
Best Medical International, Inc.
7643 Fullerton Road
SPRINGFIELD VA 22153

Re: K042786
Trade/Device Name: Best Model No. 81-01 Series Ir-192 Sources
Regulation Number: 21 CFR 892.5730
Regulation Name: Radionuclide brachytherapy source
Regulatory Class: II
Product Code: 90 KXK
Dated: September 23, 2004
Received: October 6, 2004

Dear Mr. Ramaswamy:

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/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

BEST MEDICAL INTERNATIONAL, INC.

Appendix 2

Indications for Use Form

510 (k) Number: Reference K910710 K042786

Device Name: BEST Model No. 81-01 Series Sources

Indications For Use:

The BEST Model No. 81-01 Series Sources are intended for the delivery of therapeutic doses of gamma radiation for the purpose of brachytherapy treatments (e.g., interstitial, intracavitary, intralumen, or topical radiation therapy).

(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)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K042786