

K972804

MGS RESEARCH, INC.

OCT 23 1997

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510(k) Summary

Date: 07/01/97
Applicant: MGS Research, Inc., 1, Orchard Park Road, Madison, CT 06443
Contact: Marek J. Maryanski, President
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Trade Name: BANG Polymer-Gel Dosimeter.

Common Name: Gel dosimeter for recording radiation dose distributions in three dimensions.

Classification Name: Therapeutic X-Ray System (Accessory).

Substantial Equivalence: The BANG Polymer-Gel Dosimeter is substantially equivalent to the automated water-tank scanner produced by the Wellhofer Corp. (approved as K945321).

Description of Device: Polymer-Gel Dosimeters consist of various monomers dispersed in a gelatin matrix. These monomers are polymerized by the free radicals produced by ionizing radiations, and the extent of polymerization is proportional to the absorbed dose. Both the NMR and optical properties of the irradiated gel are thus changed, and dose distributions may be imaged and quantitated using magnetic-resonance imaging (MRI) or computerized optical tomographic scanning (currently under development by MGS). The polymerization converts the original solution of monomers into a suspension of microparticles that are each much smaller than one micron, and which are fixed in space by the gel, and so the resolution of polymer-gel dosimeters is limited mainly by the imaging device employed. Using a standard head coil and a clinical MRI, pixel sizes on the order of 1 mm are obtained when imaging 2-4 liter gels. For the higher resolution that may be required for brachytherapy sources, gels of about 0.5 liters can be imaged in small-bore, higher-frequency MRI's and pixel sizes of fractions of a millimeter obtained.

Polymer-Gel Dosimeters contain only organic molecules and water, and so their average and effective atomic numbers, and mass densities are, depending upon the specific formulation, very nearly the same as that for muscle tissue. Also, their dose-

response curves exhibit little or no radiation-quality dependence over the range of x- and gamma-ray energies employed in radiation therapy, nor do they show any dose-rate dependence for dose rates in the range 0.06-16 Gy/min. Of equally great importance is that polymer gels take the shape of their containers which could simulate various parts of the anatomy, and even contain bone and air cavities. This latter feature will provide data not obtainable by any other practical means, and which can provide a benchmarks for treatment-planning-computer algorithms.

As polymerization of the monomers in polymer-gel dosimeters is inhibited by oxygen, it is essential that the vessel that contains the gel be oxygen-free when it is filled and impermeable to oxygen during the period of irradiation and for one hour post-irradiation during which time polymerization goes to completion. This requirement places severe constraints upon the techniques employed for gel preparation, and upon the materials and methods of fabrication of the gel vessels. At the present time, MGS provides polymer gels in 2-liter, spherical glass vessels for confirmation of stereotactic radiosurgery, and 1.0-liter glass bottles for brachytherapy-source dosimetry. These vessels are shipped in nitrogen-filled pouches made from a unique aluminum/Saran/polyethylene foil. The fabrication of vessels made from Borex plastic, a product of the BP Chemicals Corp., and which is impermeable to oxygen, is also possible.

The images recorded by polymer-gel dosimeters are permanent thus permitting comparisons between, for example, the dose distributions for a particular x-ray beam which were made even years apart.

Technological Comparison: In the automated water-tank scanner the water provides the near-tissue-equivalent absorbing and scattering medium, and a small detector (ionization chamber or silicon diode) makes point-by-point measurements of dose in a matrix of points contained in a single plane. Isodose curves are obtained using computer programs which interpolate between the measured points so as to locate a new series of points, each of which represents a dose that is a specified fraction of the maximum dose. These isodose points are then connected smoothly to yield isodose curves. Should a full three-dimensional dose distribution be required, a number of planes parallel to the plane containing the central axis of the beam would be scanned, and the isodose curves from these planes connected by a similar interpolation process.

By comparison, the Polymer-Gel Dosimeter comprises both the absorbing and scattering medium and the radiation detector, the doses to all points in the gel medium being recorded, i. e., polymerization of monomers, simultaneously during the course of irradiation. Isodose curves in one or more arbitrarily specified planes are obtained using magnetic-resonance imaging (MRI) the first step of which is to generate a map of the proton relaxation rate where each pixel in this map has a relaxation rate which is proportional to the dose delivered to that pixel. Next, this relaxation map is converted to a dose map by application of the dose-response curve (R_2 vs Gy) that is appropriate to the polymer gel employed. This curve is obtained from measurements

of a calibration kit of identical gel irradiated to known doses. Isodose curves are now generated using an algorithm that is similar to the one employed with the water-tank scanner. Should a full three-dimensional dose distribution be required, dose maps would be generated for a series of closely-spaced parallel image planes, and the isodose curves from these planes connected by a similar interpolation process. Due to the small voxel size, 1 X 1 X 3 mm, obtained by MRI, the resolution achievable with polymer-gel dosimeters is generally higher than that achievable with water-tank scanners.

Non-Clinical Performance Data: Dose response curves and central-axis depth-dose curves determined for high-energy x-ray and electron beams using the Wellhofer automated water-tank scanner and the Polymer-Gel Dosimeter are shown in the accompanying reprint "Radiation therapy dosimetry using MRI of polymer gels" published in *Medical Physics*, 23, 699-705, figures 3 - 5 (see Exhibit 5 in Appendix A, attached).

Conclusion: The close proximity of the above data sets obtained using the Wellhofer system and the Polymer-Gel Dosimeter is well within the experimental uncertainty limits of these devices, and it is the conclusion of MGS Research that the Polymer-Gel Dosimeter is substantially equivalent to the Wellhofer automated water-tank scanner for the determination of dose distributions produced by x-ray, gamma-ray and electron beams.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 23 1997

Marek J. Maryanski
President
MGS Research, Inc.
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Madison, CT 06443

Re: K972804
BANG Polymer-Gel Dosimeter
Dated: July 1, 1997
Received: July 28, 1997
Regulatory Class: II
21 CFR 892.5050/Procode: 90 IYE

Dear Ms. Maryanski:

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 requirement, 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/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

510(k) Number (if known): K972804

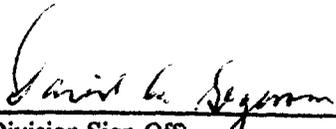
Device Name: BANG Polymer-Gel Dosimeter

Indications For Use:

Polymer-gel dosimeters may be used for quality assurance procedures for radiotherapy treatments whenever three dimensional dose distributions are required. They can be used for routine measurements of radiation dose distributions produced by irradiation devices delivering doses in the range 0-30 Gy.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K972804

Prescription Use
(Per 21.CFR 801.109)

OR

Over-The-Counter Use