



**3. Classification**

This device is classified as a class II device according to 21 CFR 892.5700 .

**4. Performance Standards**

Performance standards for applicators for remote controlled afterloading brachytherapy have not been established by the FDA under Section 514 of the Food, Drug and Cosmetic Act.

**5. Intended Use and Device Description**

The Mick Radio-Nuclear Instruments, Inc. HDR Contour TP Template and Implant Accessories are intended for use in Brachytherapy. The delivery of radiation therapy to the Prostate via High Dose Rate Remote Afterloading (HDR) requires not only proper visualization and localization of the treatment volume, but precise dosimetry and then a stable delivery system from which treatment can be administered. The Mick Radio-Nuclear "HDR Contour TP Template and Implant Accessories are designed to act as accessories to commercially available HDR Systems (Varian K952913; Gammamed K891131/A; Nucletron K852842). By providing a template that can be attached to the patient perineum as described in the currently cleared H.A.M. Applicator (Mick Radio-Nuclear Instruments K961601), and hold multiple HDR needles in a pre-defined array for treatment delivery, again as cleared in the H.A.M. Applicator (Mick Radio-Nuclear Instruments K961601) the Contour TP Template System provides a system for needle placement in the use of HDR for radiotherapy treatments of the Prostate.

**6. Biocompatibility**

No new issues of biocompatibility are raised with regard to this device.

**7. Summary of Substantial Equivalence**

This device is similar in design and construction, utilizes the identical materials, and has the same intended use and performance characteristics to the predicate devices. No new issues of safety or effectiveness are introduced by using this device.



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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850Felix Mick  
President  
Mick Radio-Nuclear Instruments, Inc.  
P.O. Box 99  
Bronx, N.Y. 10465Re: K993400  
HDR Contour TP Template System  
Dated: October 7, 1999  
Received: October 8, 1999  
Regulatory class: II  
21 CFR 892.5700/Procode: 90 JAQ

Dear Mr. Mick:

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 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). 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,

CAPT Daniel G. Schultz, M.D.  
Acting 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

510(k) Number: *To be assigned*

*K993400*

Device Name: HDR Contour TP Template and Implant Accessories

### Indications for Use:

The use of sealed Radioisotopes to treat tumors within the body has been documented and published since the turn of the century. Modern era Radiation Therapy has developed delivery systems using isotopes of Cesium, Iridium, Iodine, and Gold to name a few examples. Many tumors now are treated by internal exposure to radiation emitted from sealed radioactive sources. Two common modalities for this are Low Dose Rate and High Dose Rate remote afterloading. One common use of high dose rate remote afterloaders is in the treatment of cancer of the prostate. The system described in this 510(k) has been developed to work with commercially available high dose rate remote in the treatment of the Prostate.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use:  or Over-The Counter Use:  (Per 21 CFR 801.109)

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

510(k) Number *K993400*