DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

file

Food and Drug Administration
Rockville MD 20857

Office of the Commissioner
5600 Fishers Lane
Room 14-105, HF-7

June 5, 1996

Re: Request For Designation
TheraSphere® Administration System
Sponsor: Nordion International Inc.
Our File: RFD-96-10

Dear Ms. [ ]

We have completed our review of the above-referenced request for a product jurisdiction determination, accepted for filing on April 30, 1996. The request was submitted by [ ] on behalf of Nordion International, Inc.

The TheraSphere® Administration System ("System") consists of glass microspheres containing yttrium-90 as an "integral constituent of the insoluble glass." The System also includes an administration set for the administration of the activated microspheres to the patient. The System is intended for use in the treatment of hepatic neoplasia in patients who have appropriately positioned hepatic arterial catheters.

The request for designation noted that it was "Nordion's opinion that TheraSphere® Administration System meets the criteria of a device" in that the product "does not achieve its primary intended purpose through chemical action within or on the body, or by being metabolized."

After considering the information in the request, and consulting with the appropriate officials in the Center for Devices and Radiological Health (CDRH) and the Center for Drug Evaluation and Research (CDER), I am designating CDRH as the

agency component with primary jurisdiction for the premarket review and regulation of the System.

The System will be regulated under the medical devices provisions of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 360 et seq.).[1] Any clinical investigations of the system should be conducted in accordance with the investigational device exemption requirements in 21 C.F.R. Part 812.

The Division of Reproductive, Abdominal, Ear, Nose, and Throat, and Radiological Devices in the Office of Device Evaluation, CDRH, will be the primary reviewing division. DRAERD will consult with reviewing staff in CDER, as necessary.

For further information about the review process, contact Robert Phillips, Ph.D., Supervisory Physicist, DRAERD, CDRH at 301-594-1212. Please include a copy of this letter in your next submission to CDRH. Submissions should be addressed to the Document Mail Center (HFZ-401), 9200 Corporate Boulevard, Rockville, MD 20850.

If you have any questions about this letter, please do not hesitate to call me at 301-827-3390.

Sincerely yours,

Steven H. Unger
Deputy, Office of the Chief
Mediator and Ombudsman

cc: Robert Phillips, Ph.D.

---

[1] In telephone conversations with this office, C) asked about the eligibility of the System for expedited review. I am informed by CDRH that cancer therapeutics may be appropriate candidates for expedited review under the "Expedited Review" Blue Book Memorandum. See General Program Memorandum #G94-2. This matter should be discussed with the review division at an appropriate time in product development.