DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Office of the Chief Mediator and Ombudsman
5600 Fishers Lane, (HF-7)
Rockville, MD 20857

Food and Drug Administration
Rockville MD 20857

April 6, 1998

Sanford Brown
Regulatory Affairs Manager
Oridion Medical Ltd.
Har Hotzvim Science Based Industrial Park
POB 45025
91450 Jerusalem, Israel

RE: Request for Designation
Oridion Breath ID Test Kit
Our File: RFD 98-03

Dear Mr. Brown:

We have completed our review of the above-referenced request for a product jurisdiction determination, accepted for filing on February 4, 1998.

The Oridion Breath ID Test Kit is a breath test system that consists of (1) a medical device for measuring and computing the ratio of $^{12}CO_2$ and $^{13}CO_2$ in a patient's exhaled breath and (2) a test kit that contains ^{13}C urea and a nasal cannula that is connected to the Breath ID device during the breath test. The breath test system is an in vivo diagnostic test for the identification of patients with Helicobacter pylori (H. pylori) infection.

Oridion stated that the information in the request for designation "shows CDRH should be the lead center" for review of the marketing application(s) for the test system.

After considering the information in the above-referenced request, and consulting with the appropriate officials in CDRH and the Center for Drug Evaluation and Research, we conclude that the Oridion Breath ID measuring device and the test kit together constitute a combination product whose primary mode of action is that of a device. As the primary mode of action of the combination product is that of a device, premarket review and regulation responsibility for the product is assigned to CDRH. The breath test system will be regulated by CDRH using both medical device and new drug review legal authority, as follows: (1) the test kit, including the ^{13}C urea drug component, will be reviewed and regulated under the new drug provisions of the Federal Food, Drug, and

Cosmetic Act (21 U.S.C. 355)[1]; and (2) the combination of the test kit and measuring device will be regulated and subject to review under the 510(k) premarket notification provisions of the medical device section of the Act.

Any clinical investigations of the system should be conducted under the investigational device provisions of the law (21 CFR Part 812); a separate investigational new drug application (IND) is not required.

Submissions for the system should be made to CDRH. The Division of Clinical Laboratory Devices (DCLD), Office of Device Evaluation, CDRH will be the primary review group. DCLD will conduct its review in consultation with review staff in CDER, as appropriate. DCLD will provide guidance on the format and content of all required investigational and marketing submissions. For further information, contact Kaiser Aziz, Associate Director, DCLD, CDRH, 2098 Gaither Road, HFZ-440, Rockville, MD 20850, or by telephone at 301-594-3084.

Please include a copy of this letter in future submissions to CDRH.

Finally, you should be aware that a new drug application for the test kit may be subject to user fees, in accordance with the requirements of the Prescription Drug User Fee Act of 1992. For questions about user fees, contact Mike Jones, Consumer Safety Officer, CDER, 1451 Rockville Pike, HFD-005, Rockville, MD 20852, or by telephone at 301-594-2041.

If you have any questions about this letter, please telephone me at 301-827-3390.

Sincerely yours,

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

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[1] Please note that ^{13}C Urea is covered by an approved new drug application. The new drug application for the drug product is covered by marketing exclusivity that expires September 17, 2001. FDA may not be able to accept an abbreviated application (ANDA) for the ^{13}C Urea drug product until expiration of the market exclusivity period. Eligibility of the product for ANDA review should be discussed with Gordon Johnston, Deputy, Office of Generic Drugs, CDER, 7500 Standish Place, HFD-601, Rockville, MD 20855, or by telephone at 301-594-0183.