



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Office of the Commissioner  
5600 Fishers Lane  
Room 14-105, HF-7  
Rockville, Maryland 20857  
301-827-3390

Food and Drug Administration  
Rockville MD 20857

June 16, 1997

[ ]  
Ortho Diagnostic Systems, Inc.  
1001 U.S. Highway 202  
Raritan, NJ 08869-0606

Re: Request for Designation  
In Vitro Diagnostic Assays  
Our file: 97.006

Dear Ms. [ ]

This letter responds to your April 7, 1997 request for designation of [ ] immunodiagnostic kits, submitted on behalf of Ortho Diagnostic Systems, Inc. (a subsidiary of Johnson & Johnson). We have completed our review of your request. The Center for Devices and Radiological Health will be assigned primary jurisdiction for the premarket review of the [ ] hepatitis immunodiagnostic kits. [ ]

The [ ] immunodiagnostic kits covered by this request for designation are to be dedicated to the VITROS ECi Immunodiagnostic System, a clinical diagnostic instrument platform that performs continuous, random access, and STAT immunodiagnostic fluid specimen analysis using chemiluminescence detection technology.<sup>1</sup> Johnson & Johnson has previously obtained clearance of other immunodiagnostic kits for use with the VITROS ECi Immunodiagnostic System, including, among others, a total thyroid kit, a Follicle Stimulating Hormone kit, and a reproductive endocrinology kit. According to Ortho, the System is specifically designed to address the management of the complex workload of a clinical diagnostic laboratory, and is neither compatible with testing systems or work flows employed in licensed blood or plasma donor centers, nor intended for that use.

The kits contain individual microwells coated with one of a variety of antigens or antibodies, an assay reagent, and a conjugate reagent. The System [ ]

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<sup>1</sup> The VITROS ECi Immunodiagnostic System is the subject of premarket notification k962919, held by Johnson & Johnson Clinical Diagnostics, Inc., and cleared by FDA on October 18, 1996.

Ortho requested designation of [ ]  
VITROS Immunodiagnostic Products Hepatitis B Surface Antigen (HBsAG)  
Controls, Calibrators and Reagent Pack;

VITROS Immunodiagnostic Products Antibody (IgM) to Hepatitis B Core Antigen  
(IgM anti-HBc) Controls, Calibrators and Reagent Pack;

VITROS Immunodiagnostic Products Antibody to Hepatitis B Core Antigen (anti-  
HBc) Controls, Calibrators and Reagent Pack;

VITROS Immunodiagnostic Products Antibody to Hepatitis C Virus (anti-HCV)  
Controls, Calibrators and Reagent Pack;

VITROS Immunodiagnostic Products Antibody to Hepatitis B Surface Antigen  
(anti-HBs) Controls, Calibrators and Reagent Pack

Ortho recommended that [ ]

[ ] the Center for Devices and Radiological Health (CDRH) be  
designated the agency component with primary jurisdiction of the [ ]  
hepatitis immunodiagnostic kits. After considering the information Ortho submitted,  
and conferring with the two affected centers, I am in agreement with Ortho's  
recommendation. Therefore, I am designating [ ]

[ ] CDRH as the  
agency component with primary jurisdiction for the premarket review and regulation  
of the [ ] hepatitis immunodiagnostic kits. [ ]

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regulated under the medical device provisions of the Federal Food, Drug, and Cosmetic Act.


Please submit a copy of this designation letter with your initial submissions  
to [ ] [CDRH.] [ ]

The Microbiology Branch of the Division of Clinical Laboratory Devices, Center for Devices and Radiological Health will review the marketing applications covering [ ] hepatitis immunodiagnostic kits. For further information, contact the Microbiology Branch at 301-594-2096.

Please note that this designation applies only to the designated hepatitis immunodiagnostic products when they are intended for use as aids in the diagnosis and management of individual patients, and not for blood screening. CBER has informed this office, however, that technology developed for individual patient diagnosis and management may also be useful in blood screening. It is part of CBER's mission to facilitate the development and approval of the most sensitive and specific blood screening products possible. If Ortho is considering expanding the intended use of these products to include blood screening, it may wish to discuss the relevant data requirements with CBER's Office of Blood Research and Review, at 301-827-3518. If Ortho chooses to submit a marketing application covering a blood screening indication for the hepatitis immunodiagnostic products, FDA will make an additional agency determination of the regulatory requirements applicable to the new indications in accordance with the Intercenter Agreement between the Center for Biologics Evaluation and Research and the Center for Devices and Radiological Health.

If you have any questions about this matter, please contact Ms. Suzanne O'Shea, of this office, at 301-827-3390.

Sincerely yours,



Amanda Bryce Norton  
Chief Mediator and Ombudsman