



DEPARTMENT OF HEALTH & HUMAN SERVICES

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Food and Drug Administration  
10903 New Hampshire Avenue  
Document Mail Center - WO66-G609  
Silver Spring, MD 20993-0002

Eiken Chemical Co., Ltd.  
c/o TUV SUD America, Inc.  
Mr. Stefan Preiss  
1775 Old Highway 8 NW  
New Brighton, Minnesota 55112-1891

JAN 08 2010

Re: k092330  
Trade/Device Name: OC-Sensor DIANA IFOB Test  
Regulation Number: 21 CFR 864.6550  
Regulation Name: Occult blood test  
Regulatory Class: Class II  
Product Code: OOX  
Dated: October 16, 2009  
Received: October 19, 2009

Dear Mr. Preiss:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

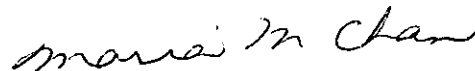
Page 2 – Mr. Preiss

CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Maria M. Chan, Ph.D.  
Director  
Division of Immunology and Hematology Devices  
Office of *In Vitro* Diagnostic Device Evaluation and Safety  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known):

Device Name: OC-SENSOR DIANA iFOB Test

Indications for Use:

"OC-Sensor DIANA iFOB Test" is designed to be used together as an immunoassay test system. The test system is intended for the qualitative detection of fecal occult blood in feces by professional laboratories. The automated test is used for the determination of gastrointestinal (GI) bleeding, found in a number of gastrointestinal disorders (GI), e.g. colitis, polyps, and colorectal cancer.

The OC-Sensor DIANA iFOB test is recommended for use in:

1. Routine physical examinations
2. Monitoring bleeding in patients
3. Screening for colorectal cancer or gastrointestinal bleeding


Prescription Use   ✓    
(Part 21 CFR 801 Subpart D)

AND/OR Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

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

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

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Division Sign-Off

Section 4.0 – Indications for Use

Office of In Vitro Diagnostic  
Device Evaluation and Safety

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