K092817

MAR - 9 2010

510(k) Summary
POC-AS10 Auto sampler
(Modification of POCone Infrared Spectrophotometer)

1. SPONSOR

Otsuka Pharmaceutical Co., Ltd.
2-9 Kanda-Tsukasamachi, Chiyoda-ku
Tokyo 101-8535 Japan

Contact Person:	Mr. Shinji Iizuka Operating Officer, General Manager
Telephone:	81 3 6361 7311
E-mail:	iizukas@otsuka.jp

Date Prepared: September 11, 2009

2. DEVICE NAME

Proprietary Name:	POC-AS10 Auto sampler (Accessory to POCone Infrared Spectrophotometer)
Common/Usual Name:	Infrared Spectrophotometer
Classification Name:	Colorimeter, Photometer, or Spectrophotometer for Clinical Use

For use of the POCone Infrared Spectrophotometer in conjunction with commercially available Meretek ^{13}C-urea breath tests for the detection of *Helicobacter pylori* (*H. pylori*) infection, the following are also applicable:

Common/Usual Name:	Analysis System for Use with ^{13}C-Urea Breath Test
Classification Name:	Urea Breath Test

3. PREDICATE DEVICES

POCone Infrared Spectrophotometer (parent device)

UBiT-IR300 Infrared Spectrometry System

4. DEVICE DESCRIPTION

The POC-AS10 Auto sampler is an optional accessory to the POCone Infrared Spectrophotometer. The POCone Infrared Spectrophotometer is an in vitro diagnostic device designed to measure changes in $^{13}CO_2$ content in breath CO_2 gas by infrared spectroscopic analysis. The POC-AS10 Auto sampler expands the number of breath collection bags that can be set up and analyzed by the POCone Infrared Spectrophotometer. By connecting the POC-AS10 Auto sampler to the POCone Infrared Spectrophotometer, up to ten pairs of breath collection bags (20 bags total) can be set up at one time.

5. INTENDED USE/INDICATIONS FOR USE

The POCone Infrared Spectrophotometer is an in vitro diagnostic device designed to measure changes in $^{13}CO_2$ content in breath CO_2 gas by infrared spectroscopic analysis. The POC-AS10 Auto sampler expands the number of breath collection bags that can be set up and analyzed by the POCone Infrared Spectrophotometer.

The POCone Infrared Spectrophotometer is intended for use in conjunction with commercially available Meretek ^{13}C-urea breath tests for the detection of *Helicobacter pylori* (*H. pylori*) infection. The POCone Infrared Spectrophotometer is suitable for use in both point of care and clinical laboratory settings.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The POC-AS10 Auto sampler is an optional accessory to the POCone Infrared Spectrophotometer. The POC-AS10 Auto sampler, connected to the POCone Infrared Spectrophotometer, is substantially equivalent to the parent device based on the intended use and technological characteristics.

7. PERFORMANCE TESTING

Testing activities for the POC-AS10 Auto sampler consisted of electrical testing of the POC-AS10 Auto sampler unit and system level nonclinical testing with the POC-AS10 Auto sampler connected to the POCone Infrared Spectrophotometer. The nonclinical testing consisted of reproducibility and carry-over studies using standard gas samples. The testing demonstrated that the POC-AS10 Auto sampler accessory to the POCone Infrared Spectrophotometer successfully fulfilled prospectively defined verification and validation activities.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Building 66
Silver Spring, MD 20993

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Cynthia A. Sinclair
Medical Device Consultants
On behalf of: Otsuka Pharmaceutical Co., Ltd.
49 Plain Street
North Attleboro, MA 02760

Re: K092817
Trade/Device Name: POCone Infrared Spectrophotometer, POC-AS10 Auto sampler
Regulation Number: 21 CFR 866.3110
Regulation Name: Campylobacter fetus serological reagents
Regulatory Class: Class I
Product Code: MSQ, JJQ
Dated: February 5, 2010
Received: February 12, 2010

Dear Ms. Sinclair:

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.

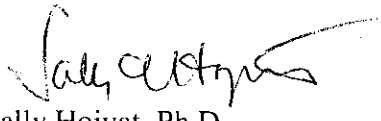
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's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



Sally Hojvat, Ph.D.
Director
Division of Microbiology Devices
Office of In Vitro Diagnostics
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K092817

Device Name: POC-AS10 Auto sampler (Accessory to POCone Infrared Spectrophotometer)

Indications for Use:

The POCone Infrared Spectrophotometer is an in vitro diagnostic device designed to measure changes in $^{13}CO_2$ content in breath CO_2 gas by infrared spectroscopic analysis. The POC-AS10 Auto sampler expands the number of breath collection bags that can be set up and analyzed by the POCone Infrared Spectrophotometer.

The POCone Infrared Spectrophotometer is intended for use in conjunction with commercially available Meretek ^{13}C-urea breath tests for the detection of *Helicobacter pylori* (*H. pylori*) infection. The POCone Infrared Spectrophotometer is suitable for use in both point of care and clinical laboratory settings.

Prescription Use X AND/OR Over-The-Counter Use___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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