510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

A. 510(k) Number:

K092817

B. Purpose for Submission:

This 510k is for a modification to a previously cleared device. The modification is for use of the POC-AS10 Auto sampler with the POCone Infrared Spectrophotometer.

C. Measurand:

$^{13}CO_2$ content of breath CO_2 gas due to the presence of H. pylori.

D. Type of Test:

Quantitative infrared spectroscopic analysis

E. Applicant:

Otsuka Pharmaceutical Co., Ltd

F. Proprietary and Established Names:

POCone Infrared Spectrophotometer and POC-AS10 Auto sampler

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
MSQ	Class I	21 CFR 866.3110	Microbiology (83)
JJQ	Class I	21 CFR 862.2300	Chemistry (75)

H. Intended Use:

1. Intended 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.

2. Indication(s) 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.

3. Special conditions for use statement(s):

The POCone Infrared Spectrophotometer is for prescription and point-of-care use.

4. Special instrument requirements:

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POCone Infrared Spectrophotometer
POC-AS10 Auto sampler

I. Device Description:

The POCone Infrared Spectrophotometer is a compact analyzer designed for on-site performance of the $^{13}CO_2$-urea breath test. For the test the patient provides an initial breath sample (reference or baseline) by blowing into an Otsuka breath collection bag. After ingestion of ^{13}C-labeled urea and after a specified period of time, another breath sample is provided (test or post dose) by blowing into a second breath collection bag. The bag includes a mouthpiece and port compatible with the inlet ports of the POCone. The mouthpiece end of the bag has a one way valve which prevents loss of breath sample. The POCone has 2 ports for attaching the breath collection bags. After attachment, the reference and test breath samples are automatically injected and measurements are performed by the POCone for approximately 2 minutes. User interface with the POCone is by means of a keypad and LCD screen on the front panel. An internal printer is provided to allow subject information and test results to be printed.

The POC-AS10 Auto sampler is an optional accessory that expands the number of breath collection bags that can be set 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 can be set up at one time.

J. Substantial Equivalence Information:

1. Predicate device names:
POCone Infrared Spectrophotometer
UBiT-IR300 Infrared Spectrophotometer

2. Predicate 510(k) numbers:

   K041148, K013371

3. Comparison with predicate:

Characteristics	POC-AS10 Auto sampler (connected to POCone Infrared Spectrophotometer)		POCone Infrared Spectrophotometer (Parent Device)	UBiT-IR300 Infrared Spectrometry System	
Intended Use	Measure changes in $^{13}CO_2$ content in breath for detection of *H. pylori* infection				
Reagent	^{13}C-Urea (MERETEK UBT Breath Test for *H. pylori* — K972352 and K952220)				
Test Sample	Breath sample in specially designed breath collection bags				
Sample Amount	Not less than 120 mL/bag		Not less than 120 mL/bag	Not less than 120 mL/bag	
Number of Sample Ports for Attachment of Breath Collection Bags	POCone: 2 (1 pair of bags) POC-AS10: 20 (10 pairs of bags)		2 (1 pair of bags)	UBiT-IR300: 2 (1 pair of bags) UBiT-AS10: 20 (10 pairs of bags)	
Detection Method	Infrared spectrophotometer (POCone)		Infrared spectrophotometer (POCone)	Infrared spectrophotometer (UBiT-IR300)	
Cut-Off Value (using MERETEK UBT Breath Test)	2.4 Delta Over Baseline		2.4 Delta Over Baseline	2.4 Delta Over Baseline	
User Setting	Point of Care or Clinical Laboratory		Point of Care or Clinical Laboratory	Point of Care or Clinical Laboratory	
System Components	• POCone Infrared Spectrophotometer (with built-in computer) • POC-AS10 Auto sampler • Breath Collection Bag		• POCone Infrared Spectrophotometer (with built-in computer) • Breath Collection Bag	• UBiT-IR300 Infrared Spectrophotometer (with built-in computer) • UBiT-AS10 Auto sampler • Breath Collection Bag	
User Interface	Keypad and LCD screen on front panel of POCone		Keypad and LCD screen on front panel of POCone	Keypad and LCD screen on front panel of UBiT-IR300	
Dimensions: Width Depth Height Weight (approximate)	POCone: 220 mm 361 mm 272 mm 10 kg	POC-AS10: 280 mm 330 mm 230 mm 6.1 kg	POCone: 220 mm 361 mm 272 mm 10 kg	UBiT-IR300: 310 mm 620 mm 310 mm 22.5 kg	UBiT-AS10: 400 mm 272 mm 355 mm 6.3 kg
Measuring Time (approximate for 1 pair of bags)	2 minutes		2 minutes	5-6 minutes	
Regulatory Status	K092817		K041148	K013371	

K. Standard/Guidance Documents Referenced:

- IEC 61010-1: Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1. General requirements.
- IEC 61010-2-101: Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 2-101. Particular requirements for in vitro diagnostics (IVD) medical equipment.

L. Test Principle:

The principle of measurement of the POCone spectrophotometer is based on the utilization of the difference between the specific absorptions of $^{13}CO_2$ and $^{12}CO_2$ in the infrared region. When breath samples collected in breath collection bags are placed on the inlet ports of the POCone, the instrument draws in samples from the 2 bags in sequence. It automatically

removes moisture from the breath and meters the samples into the measurement cell. Light from a temperature-stabilized infrared light source passes through a mechanical chopper and then through each gas sample. The intensity of the transmitted signal is measured by a cooled infrared detector. The instrument measures absorption of breath gas by calculating the ratios of $^{13}CO_2/^{12}CO_2$ for the reference breath gas and sample breath gas. The difference between the ratios is calculated to obtain the final measurement result, which is reported as $\Delta^{13}CO_2$ and expressed as delta per mil (‰) or delta over baseline (DOB). Internal algorithms calculate the isotope ratios and report the result to the display screen and on an integral printer.

M. Performance Characteristics:

1. Analytical performance:

a. Reproducibility:

A reproducibility study was performed to assess the within-run precision of the POCone with the POC-AS10 connected by replicate measurements of standard gas samples. Four standard gas samples with different $^{13}CO_2/^{12}CO_2$ ratios containing 3% CO_2 were used in the study. The values for the standard gas samples were determined by the conventional GIRMS method. Among these standard gas samples, the one having the lowest $\delta^{13}C$ value (-32.7‰) was used as the reference gas and the $\Delta^{13}C$ values were calculated for the other 3 standard gas samples (Δ1.7‰, Δ13.7‰, Δ26.7‰) in addition to Δ0‰ gas for zero balance check. Measurements on each of the gases were performed using three different sets of POCone with POC-AS10, paired with reference gas sample.

The standard deviation for the four gas values measured ranged from 0.06‰ to 0.17‰. No significant difference in the standard deviations among the three devices or the gas values was evident.

b. Linearity/assay reportable range:

Linearity established in K041148. This modification did not affect Linearity or reportable range.

c. Traceability, Stability, Expected values (controls, calibrators, or methods):

These were established in K041148. This modification did not affect these parameters.

d. Detection limit:

The Detection Limit was established in K041148. This modification did not affect this parameter.

e. Analytical specificity:

This was established in K041148. This modification did not affect analytical specificity.

f. Assay cut-off:

2. Comparison studies:

Studies were presented in K041148. This modification did not affect the data.

3. Clinical studies:

Clinical studies were presented in K041148. This modification did not affect these parameters.

a. Clinical Sensitivity:

b. Clinical specificity:

c. Other clinical supportive data (when a. and b. are not applicable):
Not applicable.

4. Clinical cut-off:

Cut-off values were established in K041148. This modification did not affect the cutoff.

5. Expected values/Reference range:

These were established in K041148. This modification did not affect these parameters.

N. Instrument Name:

POCone Infrared Spectrophotometer and POC-AS10 Auto sampler

O. System Descriptions:

1. Modes of Operation:
The principle of measurement of the POCone spectrophotometer is based on the utilization of the difference between the specific absorptions of $^{13}CO_2$ and $^{12}CO_2$ in the infrared region. When breath samples collected in breath collection bags are placed on the inlet ports of the POCone, the instrument draws in samples from the 2 bags in sequence. It automatically removes moisture from the breath and meters the samples into the measurement cell. Light from a temperature-stabilized infrared light source passes through a mechanical chopper and then through each gas sample. The intensity of the

transmitted signal is measured by a cooled infrared detector. The instrument measures absorption of breath gas by calculating the ratios of $^{13}CO_2/^{12}CO_2$ for the reference breath gas and sample breath gas. The difference between the ratios is calculated to obtain the final measurement result, which is reported as $\Delta^{13}CO_2$ and expressed as delta per mil (‰) or delta over baseline (DOB). Internal algorithms calculate the isotope ratios and report the result to the display screen and on an integral printer.

2. Software:

   FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

   Yes ____X___ or No _____

3. Specimen Identification:

   Patient ID can be input by key operation or ID read by barcode reader.

4. Specimen Sampling and Handling:

   Patient provides breath samples by blowing into breath collection bags. Two samples are provided namely the initial reference sample and after ingestion of C-urea, the post dose sample. Breath collection bags are manually placed on the inlet ports of the POCone or in the POC-AS10 Auto sampler for gas measurement analysis.

5. Calibration:

   The instrument self-calibrates.

6. Quality Control:

   The POCone automatically performs self-diagnostic instrument checks. It is also recommended that the precision of the instrument be checked regularly, at least once a month. Additionally each laboratory should follow procedures it has established for internal quality control

P. Other Supportive Instrument Performance Characteristics Data Not Covered In The "Performance Characteristics" Section above:

Testing for carry-over was performed on the POCone alone and with the POCone connected to the POC-AS10.

Results of carry-over testing with individual POCone devices alone as well as with the POC-AS10 demonstrated negligible carry-over and inter-device variability.

Q. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

R. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.