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K014038

Serim™ RESEARCH CORP
P.O. Box 4002, Elkhart, IN 46514-0002 • (219) 264-3440 • FAX (219) 266-6222

510(k) SUMMARY

Serim™ PyloriTek® VP Test Kit

Submitted by:

Robert J. Carrico
Serim Research Corporation
P.O. Box 4002
Elkhart, IN 46514

Phone: (574) 264-3440
Fax: (574) 266-6222

Contact person: Robert J. Carrico

Date prepared: December 5, 2001

Device Name:

Trade name: SERIM™ PyloriTek VP Test Kit
Common name: Rapid urease test
Classification name: HELICOBACTER PYLORI

Device Class

Class I

Legally Marketed Equivalent Device:

This product is very similar in design, composition and function to the Serim PyloriTek Test Kit manufactured by Serim Research Corporation which was the subject of Premarket Notification K953632.

Description of the Serim PyloriTek VP Test Kit and PyloriTek VP Positive Control Papers

Helicobacter pylori grows on the gastric mucosa and colonies can be collected with biopsies taken during gastrointestinal endoscopy. *H. pylori* produces urease which is a useful marker for gastric infections. Pyloritek VP Test Kit detects urease activity in gastric biopsy specimens.

Serim PyloriTek VP Test Kit has the following components:

Reagent strips which contain, in separate dry reagent matrices, the substrate urea (Substrate Pad) and a pH indicator (Reaction Pad). The Reaction Pad containing the pH indicator is covered by a semi-permeable membrane which allows passage of gaseous ammonia but prevents passage of gastric tissue fluid or Hydration Reagent from the Substrate Pad.

Hydration Reagent which contains a buffer that is dispensed on the Substrate Pad prior to performing the test.

Reaction Chamber which is a plastic device that holds developing strips and provides solid contact between the gastric biopsy, the Substrate Pad and the Indicator Pad. This arrangement ensures that ammonia gas generated is directed through the semi-permeable membrane to the pH indicator.

PyloriTek VP Positive Control Paper is provided separately to be used as a quality control material with the PyloriTek VP Test Kit. This control is a 0.2 x 3.25 inch strip of paper containing dry urease, buffer and stabilizer. PyloriTek VP Positive Control is run on PyloriTek VP Test Strips separate from biopsy specimens.

Intended Use:

The PyloriTek VP Test Kit includes materials for detection of urease activity in gastric biopsy specimens for the presumptive identification of *Helicobacter pylori*. The test is for use on symptomatic patients by healthcare professionals.

Technological Comparison to Predicate Device:

The basic principles of PyloriTek VP and PyloriTek Test Kits are identical. *H. pylori* produces urease which is not present in mammalian tissues. The tests detect urease activity in gastric biopsy specimens according to the following reaction:

$$\text{Urea} + H_2O \xrightarrow{\text{Urease}} 2\,NH_3 + CO_2$$

The ammonia is detected with a pH indicator (bromophenol blue) which turns from yellow to blue at the elevated pH produced by ammonia.

Differences between the two kits are:

	Feature	PyloriTek VP Test Kit	PyloriTek Test Kit
1.	Test strip width	0.75 inch	1.0 inch
2.	Positive control	Urease dried in a separate Positive Control Paper.	Built-in urease control dried on test strip.
3.	Procedure	Apply 3 drops of Hydration Reagent to Substrate pad.	Apply 4 drops of Hydration Reagent to Substrate pad.
		Positive control is run separate from specimens.	Positive control develops simultaneously while specimens are tested.

PyloriTek VP Test Strips are 0.75 inch wide compared to 1.0 inch for PyloriTek strips. This change was made for economic reasons. The narrower strips require 3 drops of Hydration Reagent instead of 4 drops.

The built-in positive control on PyloriTek strips is replaced by a separate positive control for PyloriTek VP strips. In practice a PyloriTek VP Positive Control Paper is placed on the Reaction Pad of a PyloriTek VP strip. Hydration Reagent is applied to the Substrate Pad, the PyloriTek VP Test Strip is folded and placed in the reaction chamber. Development of dark blue color on the yellow indicator membrane within 15 minutes indicates that the PyloriTek VP Test Strip is functioning properly.

PyloriTek VP Positive Control Paper can also be used to verify the functionality of PyloriTek VP Test Strips after biopsy specimens are tested. At the end of the one hour period required for reading a PyloriTek VP Test Strip with a negative specimen the test strip is removed from the Reaction Chamber, unfolded and the positive control paper is placed on the Reaction Pad. Then the assembly is reinserted in the reaction chamber and development of dark blue color on the yellow indicator membrane within 15 minutes indicates that the PyloriTek VP test is functioning properly.

Statement of Substantial Equivalence

Replicate biopsy specimens from 84 patients were tested for *H. pylori* with PyloriTek VP and PyloriTek Test Kits. In this comparison the PyloriTek VP Test Kit had 100% sensitivity and 98.5% specificity.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Patricia Rupchock
Manager Regulatory Affairs
Serim Research Corporation
2356 Reedy Drive
Elkhart, IN 46514

FEB 0 8 2002

Re: k014038
Trade/Device Name: Serim™ PyloriTek® VP Test Kit
Regulation Number: 21 CFR 866.3110
Regulation Name: Campylobacter Fetus Serological Reagents
Regulatory Class: Class I
Product Code: LYR
Dated: December 6, 2001
Received: December 7, 2001

Dear Ms. Rupchock:

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 either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. 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 Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 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 Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K014038

Device Name: PyloriTek VP Test Kit

Indications For Use:

The PyloriTek VP Test Kit includes materials for detection of urease activity in gastric biopsy specimens for the presumptive identification of Helicobacter pylori. This test is for use on symptomatic patients by healthcare professionals.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K014038

Prescription Use ✓ OR Over-The-Counter Use___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)