**DEPARTMENT OF HEALTH & HUMAN SERVICES** Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-000

March 11, 2016

Medivators Inc.
Mr. Brent Geiger, M.S., RAC
Director of Regulatory Compliance
14605 28th Ave North
Minneapolis, MN 55447

Re: K152394
Trade/Device Name: Rapicide PA High-Level Disinfectant Test Strips
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: II
Product Code: JOJ
Dated: February 10, 2016
Received: February 11, 2016

Dear Mr. Geiger,

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact 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/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

*Tejashri Purohit-Sheth, M.D.*

**Tejashri Purohit-Sheth, M.D.**
**Clinical Deputy Director**
**DAGRID/ODE/CDRH FOR**

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement on last page.*

510(k) Number *(if known)*
K152394

Device Name
RAPICIDE PA High-Level Disinfectant Test Strips

Indications for Use *(Describe)*

The Rapicide PA High-Level Disinfectant Test Strips are used as a chemical indicator after the disinfection cycle to ensure that the Rapicide PA High-Level Disinfectant Solution is above minimum recommended concentration (850ppm peracetic acid); this ensures the disinfectant was above MRC during the entire disinfection cycle.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

MEDIVATORS
A Cantel Medical Company

# 510(k) Summary
# RAPICIDE® PA High-Level Disinfectant Test Strips


Manufacturer: Medivators Inc., A Cantel Medical Company

Address: 14605 28th Avenue North
Minneapolis, MN 55447 USA
(800) 328-3345


Date: March 11, 2016


Official Contact: Megan Dickey
Regulatory Affairs Specialist, Medivators Inc.
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Email: mdickey@medivators.com


Medivators Inc. has supplied the following information to support substantial equivalence of the Rapicide PA High-Level Disinfectant Test Strips to other test strips currently cleared for sale in the United States of America.

## 1. Submission Device Information:

Trade Name: **Rapicide PA High-Level Disinfectant Test Strips**

Common/usual Name: Chemical Indicator

Device Class: Class II

Classification Name: Physical/chemical sterilization process indicator
(21 CFR 880.2800 (b), Product Code JOJ)

## 2. Predicate Device Information:

K082988/K964264 - Rapicide PA Test Strips
K931935 –Endpoint 500 Peracetic Acid Test Indicators

## 3.Intended Use:

The Rapicide PA High-Level Disinfectant Test Strips are used as a chemical indicator after the disinfection cycle to ensure that the Rapicide PA High-Level Disinfectant Solution is above minimum recommended concentration (850ppm peracetic acid); this ensures the disinfectant was above MRC during the entire disinfection cycle.

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## 4. Description of Device:

Rapicide PA High-Level Disinfectant Test Strips have the ability to measure the disinfectant use solution concentration above 850ppm PAA. This is the minimum recommended concentration (MRC) of PAA for Rapicide PA high level disinfectant. If the solution is at or below MRC, the test strip pad will indicate a failure by turning dark grey, blue grey, violet grey, light grey, or white (no change in color). A passing result will be indicated by the test strip pad turning solid black color.

## 5. Comparison to Other Devices in Commercial Distribution Within the United States:

Rapicide PA High-Level Disinfectant Test Strips, the subject device, are substantially equivalent in function, intended use and scientific technology to its predicate devices – predicate Rapicide PA Test Strips cleared under 510(k) –K082988/K964264 and Endpoint 500 Peracetic Acid Test Indicators cleared under 510(k) – K931935.

| **Device Parameters** | **Subject Device – RAPICIDE PA High-Level Disinfectant Test Strips** | **Predicate – Rapicide PA Test Strips (K082988/K964264)** | **Predicate - Endpoint 500 Peracetic Acid Test Indicators (K931935)** |
|---|---|---|---|
| **Trade Name** | RAPICIDE PA High-Level Disinfectant Test Strips | Rapicide PA Test Strips | Endpoint 500 Peracetic Acid Test Indicators |
| **Regulation Number** | 880.2800 | 876.8520 | 878.4400 |
| **Device Class** | Class II | Class II | Class II |
| **Certification Panel** | General Hospital | Gastroenterology/Urology | General Hospital |
| **Product Code** | JOJ | FKP/LIF | JOS |
| **Single Use** | Yes | Yes | Yes |
| **Supplied sterile** | No | No | No |
| **Direct/Indirect Patient Contact** | No | No | No |
| **Active Ingredient Measured** | Peracetic Acid | Peracetic Acid | Peracetic Acid |
| **Indication for Use** | RAPICIDE PA High-Level Disinfectant Test Strips are used as a chemical indicator after the disinfection cycle to ensure that the Rapicide PA High-Level Disinfectant Solution is above minimum recommended concentration (850 ppm peracetic acid); this ensures the disinfectant was above MRC during the entire disinfection cycle. | RAPICIDE PA Test Strips are used after the disinfection cycle to ensure that the Rapicide PA disinfectant is above the minimum recommended concentration (850 ppm peracetic acid): this ensures that the disinfectant was above MRC during the entire cycle. | Endpoint 500 Peracetic Acid Test Indicators are used in determining effective levels of peracetic acid (greater than 500ppm) in dialyzer reprocessing. Concentrations of PAA 500 ppm and greater test positive and concentrations of less than 500 ppm test negative. This ensures the disinfectant was above MRC. |
| **"PASS" Indication** | Solid Black > 850ppm PAA | Dark Brown/ Black > 850ppm PAA | Blue/Gray or Blue/Black> 500ppm PAA |

| | | | |
|---|---|---|---|
| **Chemistry** | The chemical principle of the test is based on the oxidation of iodide to iodine by peracetic acid. A dark complex is obtained in the presence of starch. | The chemical principle of the test is based on the oxidation of iodide to iodine by peracetic acid. A dark complex is obtained in the presence of starch. | The chemical principle of the test is based on the oxidation of iodide to iodine by peracetic acid. A dark complex is obtained in the presence of starch. |
| **Packaging** | Aluminum Vial – 100 Strips | Aluminum Vial – 100 Strips | Aluminum Vial – 100 Strips |

## 6. Technological Comparison:

The chemical properties of the test strip chemical indicator pad in the predicates' design and the subject device's design is based on the oxidation of iodide to iodine by peracetic acid which creates a reaction of a dark color complex to indicate that recommended concentration of the disinfectant use-solution has been met. Same as the subject device, the Endpoint 500 strip threshold reactivity is modulated to give a qualitative, Pass/Fail, reading. The Endpoint 500 strip will turn blue/black, Pass indication, when Renalin concentration is 500ppm or greater. In comparison, the predicate Rapicide PA Test strips, a coupler is used where the strip reactivity is modulated to provide a continuous reaction range for disinfectant PA solutions from 100 to 1500ppm. In the Advantage Plus and Rapicide PA HLD 510(k) – K082988, the predicate Rapicide PA Test Strips are used as a quantitative indication of PA concentration where a darker color reaction indicates a higher PA concentration. The quantitative indication, different than the subject device qualitative indication, does not pose any additional risk because both types of strips indicate whether an acceptable PA concentration for the HLD use solution has been achieved.

## 7. Summary of Non-Clinical Performance Data

The performance of the Rapicide PA High-Level Disinfectant Test Strips were evaluated in Rapicide PA High-Level Disinfectant solutions at MRC and above in the following non-clinical tests. These results demonstrated that the Rapicide PA High-Level Disinfectant Test Strips are reliable and meet the guidance performance requirements similar to that of the predicate devices.

The following table summarizes the non-clinical testing performed by Medivators to demonstrate safety and effectiveness of Rapicide PA High-Level Disinfectant Test Strips in monitoring the concentration of Rapicide PA High-Level Disinfectant solution–

| **Study** | **Result** |
|---|---|
| **Dynamic Range** | **Met Acceptance Criteria:** Negative response at concentrations at or below MRC, positive response at higher concentrations |
| **Comparative Sensitivity and Specificity** | **Met Acceptance Criteria:** Comparative sensitivity and specificity of 1 |
| **Analytic Specificity – Contaminants** | **Met Acceptance Criteria:** Negative response at MRC, positive response at higher concentration |
| **Analytic Specificity – Other Germicides** | **Met Acceptance Criteria:** |

| | |
|---|---|
| | Negative response to other germicides |
| **Shelf Life** | **Met Acceptance Criteria:**<br>Met specifications after storage for labeled shelf life of 12 months (unopened). |
| **In-Use (Open Bottle) Stability** | **Met Acceptance Criteria:**<br>Met specifications after storage for labeled open bottle shelf life of one month. |

## 8. Conclusion:

Rapicide PA High-Level Disinfectant Test Strips are intended for use with Rapicide PA High-Level Disinfectant Solution and are substantially equivalent to the predicate devices, Rapicide PA Test Strips cleared under 510(k) –K082988/K964264 and Endpoint 500 Peracetic Acid Test Indicators cleared under 510(k) – K931935. Based on the intended use, technological characteristics, performance data, and nonclinical tests performed the subject Rapicide PA High-Level Disinfectant Test Strip is substantially equivalent and is as safe and as effective as the legally marketed predicate device.