RPC

Traditional 510k Premarket Notification
E-Z Chek® Ozone Test Strips (K100-0111)

FEB 25 2014

510(k) SUMMARY

Prepared:	February 05, 2014
Submitter:	Reprocessing Products Corporation (RPC)
Address:	1643 W. Modern Court Tucson, AZ 85705
Phone:	520-888-5551
Fax:	(Fax) 520-888-5557
Contact:	Michael Honstein, Chief Operating Officer
Device Trade Name:	E-Z Chek® Ozone Test Strips (K100-0111)
Common or Usual Name:	Ozone Test Strips
Device Classification Name:	Strip, Hemodialysis Water, Ozone detector
Product Code:	MSY
Class:	II
Regulation Number:	875.5665, 876.5820
Substantial Equivalence:	The Reprocessing Products Corporation (RPC) E-Z Chek® Ozone Test Strips (K100-0111) are substantially equivalent to the Ultra Low Total Chlorine (K100-0118) and E-Z Chek® Sensitive Total Chlorine (K100-0106) Test Strips
Device Description:	Device is semi-quantitative, reagent test strip comprised of a pad impregnated with chemicals, which change color upon contact with Ozone. The pad is attached to a plastic strip for handling.
Intended Use:	The Reprocessing Products Corporation (RPC) E-Z Chek® Ozone Test Strips (K100-0111) are designed to indicate the presence of ozone in water used in hemodialysis. The test strips will measure equal to 0.0, 0.05, 0.1, 0.2, 0.3, 0.4, and >0.5 mg/L.
Technological Characteristics:	The E-Z Chek® Ozone Test Strips (K100-0111) will detect ozone concentrations equal to and above 0.0 ppm for Ozone in water used to prepare dialysate. The test strip pad contains a specialized chemical reagent that reacts with Ozone in water. The reaction results in a color change which correlates to the concentration of

	ozone in the test water.
Performance:	The data confirms the product consistently generates color change which meets the color block for the reference solution concentration. These data demonstrate appropriate performance for use in hemodialysis water used in treatment.
Conclusion:	The Reprocessing Products Corporation (RPC) E-Z Chek® Ozone Test Strips (K100-0111) have the same intended use as the predicate device. Both the test strips and the meters are designed to detect the presence of ozone in water. The Reprocessing Products Corporation (RPC) E-Z Chek® Ozone Test Strips (K100-0111) has no characteristics which raise new types of safety and effectiveness questions. The Reprocessing Products Corporation (RPC) E-Z Chek® Ozone Test Strips (K100-0111) can be used to detect the presence of ozone in water.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

February 25, 2014

Reprocessing Products Corporation
Ted Williams
Director of Quality and Regulatory Affairs
1643 W. Modern Court
Tucson, AZ 85705

Re: K132344
Trade/Device Name: E-Z Chek® Ozone Test Strips (K100-0111)
Regulation Number: 21 CFR§ 876.5665
Regulation Name: Water purification system for hemodialysis
Regulatory Class: II
Product Code: MSY
Dated: February 5, 2014
Received: February 7, 2014

Dear Ted Williams,

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological 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)*
K132344

Device Name
E-Z Chek® Ozone Test Strips (K100-0111)

Indications for Use *(Describe)*
The Reprocessing Products Corporation (RPC) E-Z Chek® Ozone Test Strips (K100-0111) are designed to indicate the presence of ozone in water used in hemodialysis. The test strips will measure equal to 0.0, 0.05, 0.1, 0.2, 0.3, 0.4, and >0.5 mg/L.

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)*

Benjamin R. Fisher -S
2014.02.25 12:58:21 -05'00'

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