October 18, 2022

Reprocessing Products Corporation (RPC)
Dave Cox
Director of Quality Assurance and Regulatory Affairs
1643 W. Modern Court
Tucson, Arizona 85705

Re: K222167
Trade/Device Name: E-Z Chek Chlorine Residual Test Strips (K100-0101B)
Regulation Number: 21 CFR 876.5665
Regulation Name: Water Purification System For Hemodialysis
Regulatory Class: II
Product Code: MSY
Dated: July 19, 2022
Received: July 21, 2022

Dear Dave Cox:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for
Gema Gonzalez
Acting Assistant Director
DHT3A: Division of Renal, Gastrointestinal,
Obesity and Transplant Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222167

Device Name
E-Z Chek® Residual Chlorine Test Strips, K100-0101B.

Indications for Use *(Describe)*

E-Z Chek® Residual Chlorine Test Strips (K100-0101B) provide accurate and convenient means of measuring the concentration of free chlorine remaining in water when rinsing out equipment following disinfection. A rapid screening qualitative method will detect levels above 0.5ppm (mg/L) while the 30 second semi-quantitative method allows interpolation of concentration between 0ppm and 5ppm. The qualitative method can be used to determine that chlorine has been adequately rinsed from the equipment. The semi-quantitative method may be useful when corrective measures are undertaken on equipment retaining higher levels of chlorine for extended periods and for testing any containers disinfected with free chlorine (bleach).

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

510(k) SUMMARY
21 CFR 807.92

Prepared:	July 19, 2022
Submitter/Owner:	Reprocessing Products Corporation (RPC)
Establishment Registration Number:	2028411
Address:	1643 W. Modern Court Tucson, AZ 85705
Phone:	520-888-5551
Fax:	(Fax) 520-888-5557
Contact:	Dave Cox
Device Trade Name:	E-Z Chek® Residual Chlorine Test Strips (K100-0101B)
Device Common or Usual Name:	Residual Chlorine Test Strips
Device Classification Name:	Strip, Test, Reagent, Residuals for Dialysate, Disinfectant
Product Code:	MSY
Class:	II
Regulation Number:	876.5665
Predicate Device/Substantial Equivalence:	Serim Residual Chlorine Test Kit, 510(k) K901734.
Subject Device Description:	Reprocessing Products Corporation (RPC) E-Z Chek® Residual Chlorine Test Strips (K100-0101B) is semi-quantitative or qualitative, reagent test strip comprised of a pad impregnated with chemicals, which change color upon contact with free chlorine and combined chlorine (monochloramines). The pad is attached to a plastic strip for handling.

Traditional 510(k) Premarket Notification
Section 5 – 510(k) Summary
E-Z Chek® Residual Chlorine Test Strips
(K100-0101B)

Subject Device Indication for Use:	Reprocessing Products Corporation (RPC) E-Z Chek® Residual Chlorine Test Strips (K100-0101B) provide accurate and convenient means of measuring the concentration of free chlorine remaining in water when rinsing out equipment following disinfection. A rapid screening qualitative method will detect levels above 0.5ppm (mg/L) while the 30 second semi-quantitative method allows interpolation of concentration between 0ppm and 5ppm. The qualitative method can be used to determine that chlorine has been adequately rinsed from the equipment. The semi-quantitative method may be useful when corrective measures are undertaken on equipment retaining higher levels of chlorine for extended periods and for testing any containers disinfected with free chlorine (bleach).
Technological Characteristics Summary:	E-Z Chek® Residual Chlorine Test Strips (K100-0101B) and Serim Residual Chlorine Test Kit both react with free chlorine and monochloramines. The reagent pad on the strip is buffered to pH 6.8 and contains potassium iodide. Free chlorine oxidizes the colorless indicator compound to form a pink/purple oxidation reaction. Monochloramine oxidizes the potassium iodide to iodine, which in turn oxidizes the indicator to the colored form.
Non-clinical Performance Data:	The test data confirms the subject device and the predicate device consistently generates color change which meets the color block(s) for the reference solution concentrations tested. This data demonstrates appropriate performance for the detection of residual free chlorine in rinse water that was used in disinfection of hemodialysis equipment fluid pathways.

Traditional 510(k) Premarket Notification
Section 5 – 510(k) Summary
E-Z Chek® Residual Chlorine Test Strips
(K100-0101B)

Conclusion:	Reprocessing Products Corporation (RPC) E-Z Chek® Residual Chlorine Test Strips (K100-0101B) have the same intended use as the predicate device. Both test strips are designed to detect the presence of free chlorine in water. Reprocessing Products Corporation (RPC) E-Z Chek® Residual Chlorine Test Strips (K100-0101B) are as safe, effective, and performs as well as the predicate device. The subject device has no characteristics which raise new types of safety or effectiveness compared to the predicate device.