May 16, 2025

Byonyks Pvt Ltd
Eric Flachbart
Vice President, Regulatory Affairs
45/A XX Block Khayban-e-iqbal
Phase III DHA
Lahore, Punjab 54000
Pakistan

Re: K243371
Trade/Device Name: Byonyks X-1 APD Cycler; Byonyks Automated PD Set DS-1
Regulation Number: 21 CFR 876.5630
Regulation Name: Peritoneal Dialysis System And Accessories
Regulatory Class: Class II
Product Code: FKX, KDJ
Dated: October 30, 2024
Received: April 17, 2025

Dear Eric Flachbart:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Maura Rooney -S

Maura Rooney
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243371

Device Name

Byonyks X-1 APD Cycler;
Byonyks Automated PD Set DS-1

Indications for Use *(Describe)*

The Byonyks X-1 APD Cycler is indicated for acute and chronic peritoneal dialysis.

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.

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1 510(K) SUMMARY

This 510(k) summary is provided in conformance with 21 CFR 807.92.

2 Applicant Information

Name	Byonyks Pvt Ltd
Address	45/A XX Block Khayban-e-iqbal Phase III DHA Lahore Punjab 54000 Pakistan
Contact Telephone	+18139973230
Applicant Contact	Mr. Eric Flachbart
Applicant Contact Email	eric@byonyks.com
Preparation date	11 May 2025

3 Device Name

Trade Name	Byonyks X-1 APD Cycler. Byonyks Automated PD Set DS-1
Common Name	Peritoneal dialysis cycler
Classification Name	Peritoneal dialysis system and accessories
Regulation Number	876.5630
Product Code(s)	FKX, KDJ

4 Classification

Medical Specialty	Gastroenterology & Urology
Regulation	876.5630 - Peritoneal dialysis system and accessories
Product Code	FKX (Class 2) – System, Peritoneal, Automatic Delivery
Associated Product Code	KDJ

5 Predicate Device

The legally marketed predicate device is the Fresenius Liberty Select Cycler cleared under K181108. The Fresenius Multiple Tubing Segment (MTS) Set with stay•safe® PIN Connectors (K173651) is a reference device with respect to bonding strength of the tubing connections.

6 Indications for Use

The Byonyks X-1 APD Cycler is indicated for acute and chronic peritoneal dialysis.

7 Environment of Use

The Byonyks X-1 APD Cyler is prescribed for use in both professional healthcare Facility and Home Environment.

8 Device Description Summary:

The Byonyks X-1 APD Cycler System includes an Automated Peritoneal Dialysis Cycler and a disposable tubing set. The Byonyks X-1 APD Cycler is intended for acute and chronic peritoneal dialysis. Byonyks X-1 APD Cycler is an automated peritoneal dialysis system that uses a peristaltic pumping mechanism to infuse the dialysate (Dialyzing Solution) into the peritoneal cavity and drain it after the dialysate has dwelled within a patient's peritoneal cavity for a specified amount of time. Byonyks X-1 APD Cycler is a prescription-use-only device and the therapies administered using Byonyks X-1 APD Cycler are prescribed by a physician. The device operates according to a therapy prescription provided by the patient's physician. The device is designed to be used in dialysis clinics, outpatient care areas, and home treatment settings with dialyzing solutions approved for peritoneal dialysis. Dialysate is infused into the patient's peritoneal cavity from a dialysate bag through a surgically implanted catheter which provides a fluid connection to the device's disposable tubing set. The dialysate remains in the peritoneal cavity for the dwell time which is a programmed length of time prescribed by the patient's physician. After the dwell time has elapsed, the fluid is drained from the patient using the device's peristaltic pumping system to extract the fluid from the patient's peritoneal cavity. Peristaltic pumping mechanism of the Byonyks X-1 APD cycler assist the dialysate flow at pre- programmed flowrate up to the volume prescribed by the patient’s physicians, device continuously monitors volume of dialysate exchanges along with the fluid pressure external to the cassette of disposable set, fluid pressure detects resistance in dialysate exchanges at which pumping regulates the overall flow.

The Byonyks X-1 APD Cycler System consists of the (i) main control unit (Cycler) and the (ii) disposable set. The cumulative patient contact duration for Byonyks Automated PD Set DS-1 should not exceed 10 years.

9 Disposable Set Materials of Use:

Component	Materials	Patient Contact
Cassette	Polycarbonate (PC)	Yes
Tubing and Connectors	Polyvinyl chloride (PVC) Acrylonitrile Butadiene Styrene (ABS) Polycarbonate (PC)	Yes
Heater Bag	Polyvinyl Chloride (PVC)	Yes
Clamps	Polyoxymethylene (POM) Polypropylene (PP)	No
Connector Caps	Polypropylene (PP)	No

10 Sterility:

Just like the predicate, The Cycler is a non-sterile, multi-use device. The Disposable Set is provided sterile for single use.

10.1 Sterilization Testing (Disposable Sets)

The Disposable Sets are sterilized by exposure to ethylene oxide (EO). The sterility assurance level (SAL) is 10-6. Sterility and non-pyrogenicity are claimed for the fluid pathway of the disposable set.

10.2 EO Residual Testing

Residual testing for EO and ethylene chlorohydrin (ECh) was performed in accordance with AAMI/ANSI/ISO 10993-7:2008/(R) 2012 Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals. Acceptable results (i.e., < 4 mg/day for EO and 9mg/day for ECh) were obtained for the subject disposable sets.

10.3 Bacterial Endotoxin (Pyrogenicity) Testing

The Disposable Sets were tested for bacterial endotoxin (pyrogenicity) with Limulus Amebocyte Lysate (LAL) in accordance with USP 161 Medical Devices—Bacterial Endotoxin and Pyrogen Tests. It was determined the Disposable Sets are non-pyrogenic (0.25 EU/ml).

11 Performance Data

11.1 Cycler Performance Testing Summary

Testing conducted to support the determination of substantial equivalence for the Cycler is provided in the following table.

Test Conducted	Test Method Description
User Interface Workflow	These tests will confirm that the transitions between screens and the associated screen transition triggers are in accordance with the Byonyks X-1 APD Workflow. Additionally range checking of all data entry fields and displayed math will be verified. While there are Factory (test / setting) and Engineering (test) screens, these are excluded from the Workflow tests since they are not screens users will have access to. Functionality of the associated screens must be verified but these are outside of verification scope.
Functional	These tests will confirm that the functional specifications are verified. Requirements are 'tagged' by the Requirements Tracking Software in the Specification documents. Traces from tagged requirements to test objectives are established. Means to verify requirements may include code inspections, design inspections, unit-level / black-box testing, and formal functional testing.
Alarms	These tests will confirm that the alarm conditions are raised when expected and alarm handling is performed per specification. Note: accuracy of alarm conditions (e.g., over pressure trigger points) are evaluated separately
Fault Insertion Testing	Based upon the results of the risk analysis, hazard mitigations which are implemented as sensors or software checks will be tested by creating situations where the failure exists. Testing will ensure that Power on Self Tests (POST) performed at power up can detect the failures they are designed to catch. Additionally,

Test Conducted	Test Method Description
	software exception handling will be tested to ensure exceptions are correctly processed.
Safety System	System safety requirements including alarms, solution flow stoppage, and sensor functionality were verified according to pre- determined performance specifications
EN60601 Safety Certification	Testing will be conducted in accordance with the EN60601 family of compliance standards applicable to the Byonyks X-1 APD Device. The top-level standard for this device is EN60601-2-39 which identifies reference standards to be followed and/or modifies the requirements of the standard for APD machines. Example areas of testing include electrical safety, performance, IEC 60601-1 to confirm product safety. EMC/EMI will be conducted according to the requirements of IEC 60601-1-1. Testing will also be conducted in accordance with IEC 60601- 2-39 to confirm device performance. These tests may be conducted by an external lab, qualified to perform such procedures. Operating and storage temperature and humidity ranges will be specified prior to conducting these tests. Cleaning agents / solvents to which the device will be exposed will be specified prior to conducting these tests and the test agency will conduct tests using these agents in accordance with 60601-1 procedures. These tests will satisfy cleaning validation.
Fill and Drain Volumetric Accuracy Testing	Volumetric accuracy testing will be conducted to confirm the device delivers the specified volume in the mode specified as well as the device performs a drain within the device's specifications. Testing will be performed in each mode and across the range of fill and drain volumes. Tests will be performed to ensure the fluid flow rate within the mode specified is achieved within the accuracy specified.

Test Conducted	Test Method Description
	Fluid used in the flow accuracy testing will conform with applicable specifications and will be further detailed in the protocols themselves.
Reliability	The goal is to maximize the simulated use of the device i.e., the number of therapies run through and the number of hours of run time. To do so, we will exercise each component which has an action to perform, pump, doors, flow control mechanisms, door latch, heater etc. in an accelerated manner to ensure the design can meet the overall life requirements of the device. Other components such as the touch screen typically will have a life expectancy far longer than we require. For these components a review of the manufacturers specifications is sufficient. A reliability test plan will be developed to establish the methods to perform these evaluations.
COTS and SOUP	COTS and SOUP are verified and validated within the product. After the device has been verified and validated, verification and validation (V&V) activities must reoccur when maintenance changes are made to COTS and SOUP contained within the device. Analysis of these changes directs necessary V&V activities. The unknown logic paths and complexities of OTS Software components make it important to know that design structure or logic elsewhere in the system is not impacted. This means a full system regression test should be performed. Results of these validation activities should be documented
Validation	Validation activities are intended to ensure the device satisfies its intended use in a safe and effective manner. For this product Human Factors Simulations will be used as a means to validate the product. Human factors simulations are divided into two distinct test suites, Formative and Summative. Formative evaluations are performed in an iterative manner and are intended as a learning tool where we learn about how users interact with the device and to ascertain if any use errors will

Test Conducted	Test Method Description
	cause a hazard to the patient. It is expected that mitigations will be implemented in the design, labeling or training to lower the probability that hazards will occur. Summative trials are intended to demonstrate that the device is safe and effective to operate. Details of the human factors simulations are given in the Human Factors Validation Plan and the results including the use of risk analysis are documented in the Human Factors File.
Test Execution & Reporting	Test results are recorded in accordance with standard Good Documentation Practices. Test failures are recorded in the Helix ALM and tracked to closure. The disposition of each failure is recorded in the Test Report or maintained separately.
Re-Verification and Validation	Changes to the unit under test during verification and validation testing whether to correct failures during test or due to a new feature being added must be reviewed for impact on prior testing and regression testing performed as required. Re-verification and validation must be performed when integrated COTS and SOUP used within the device evolve. Changes to the unit under test after Verification and Validation testing have been completed are performed in accordance with applicable Design Controls.

11.2 Byonyks Automated PD Set DS-1 Performance Testing

Testing conducted to support the determination of substantial equivalence for the Disposable Set is provided in the following table.

Test Conducted	Test Method Description
Performance Test: Load to close the tubing clamp	The maximum load force (N) to close the clamp was determined using a calibrated electromechanical force gauge.
Occlusion test	The ability of the patient, solution, and drain line clamps to occlude the patient, solution lines, and drain line was determined by subjecting to a positive pressure of approximately 60 kPa and observing for leakage of air bubbles.
Bond Strength	A calibrated electromechanical force gauge was used to perform a pull-off test for each bonded engagement.
Shipping Test	A simulated shipping and distribution test was conducted per ISTA-3A standard to ensure that the product's structural integrity is maintained during shipping.
Heater Bag Seal	The ability of the heater bag to withstand 1.5X the labeled maximum positive and negative pressures under a constrained volume was determined.
Structural Integrity	The ability of the disposable sets to withstand 1.5X the labeled maximum positive and negative pressures was determined.

12 Biocompatibility Testing

Biocompatibility testing was conducted in accordance with ISO 10993-1:2018 and FDA guidance document Use of International Standard ISO 10993-1, “Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process” (08 September 2023).

The Disposable Sets are classified as externally communicating, blood path indirect, long-term contact (> 30 days), Category C devices in accordance with FDA guidance document, Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" (08 September 2023).

The following endpoints were evaluated to support the biological safety of the Byonyks Automated PD Set DS-1.

- Toxicological risk assessment following chemical characterization.
- Cytotoxicity
- Sensitization
- Irritation
- Material-Mediated Pyrogenicity
- Hemocompatibility
- Acute Systemic Toxicity
- Sub-Acute Systemic Toxicity
- Genotoxicity

13 Human Factors Validation Testing

The Byonyks X-1 APD Cycler was validated for safe and effective use in accordance with FDA guidance document Applying Human Factors and Usability Engineering to Medical Devices (03 February 2016).

14 Electrical Safety and Electromagnetic Compatibility (EMC)

Electrical Safety testing was performed in accordance with IEC 60601-1:2005. Electromagnetic Compatibility testing was performed in accordance with IEC 60601-1-2:2014. 5G Ad hoc testing in accordance with Cellular 5G – Radiated Immunity & WPT (IEC 61000-4-3) - Additional FDA Considerations for 5G Spot Frequencies. Electromagnetic Compatibility information within this submission is provided in accordance with FDA guidance document Information to Support a Claim of Electromagnetic Compatibility (EMC) of Electrically-Powered Medical Devices (11 July 2016).

15 Software Verification and Validation Testing

Unit, software, regression (system verification), and validation testing were performed to demonstrate the effectiveness of the software and to confirm operation of the machine. Software verification information within this submission is provided in accordance with the following FDA guidance documents:

- ANSI/AAMI/IEC 62304:2006+AMD1:2015: Medical device software - Software life cycle processes
- Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions [26 September 2023]
- Post market Management of Cybersecurity in Medical Devices - Guidance for Industry and Food and Drug Administration Staff. (01 October 2018)

16 Animal Studies

No animal studies were conducted.

17 Clinical Studies

No clinical studies were conducted.

18 Intended use / Indications for Use: 21 CFR 807.92(a)(5)

The Byonyks X-1 APD Cycler is indicated for acute and chronic peritoneal dialysis.

19 Indications for Use comparison: 21 CFR 807.92(a)(5)

The Indications for use for the Byonyks X-1 APD Cycler and the Fresenius Liberty Cycler are the same.

20 Technological Comparison: 21 CFR 807.92(a)(6)

The Byonyks X-1 APD Cycler and the Fresenius Liberty Cycler share the same intended use and are portable APD Cyclers intended for peritoneal dialysis therapy for renal patients.

The fundamental technology for pumping fluid in the Byonyks X-1 APD Cycler as well as the Fresenius Liberty Cycler is that a motor drives mechanical moving parts through a custom disposable set to move fluid to and from the patient's peritoneal cavity.

Each device uses a series of controllable valves to direct the flow of fluid to and from the patient. Both devices use pressure sensors to ensure the fluid pressure is within safe limits. Both devices provide warming of the fluid prior to delivery. Both devices utilize loadcells to measure the weight of fluid filled and drained from which volume and flowrate is calculated.

The volumetric accuracy of the Fresenius Liberty Cycler is +/- 2% of the fill volume and +/- 3% of the drain volume.

The volumetric accuracy of the Byonyks device is+/- 2% of the fill volume and+/- 3% of the drain volume.

Each device is powered via 100-240 VAC with an available internal lithium-ion battery pack for power interruptions, allowing patients to safely finish their therapy and the machine to save the parameters.

Each device has a color touchscreen LCD display for interfacing with users. Each device is controlled by an embedded microcomputer which controls the delivery of fluid and provides a means to program the device for a prescribed therapy.

The flow rate of both devices is pre-programmed with their respective pumping technology at a nominal rate to fill up to the prescription volume, in case during the flow any resistance in the fluid path is detected through the fluid pressure, this results in reduced or no flow. Pumping of the both devices are associated with the fluid pressure limits as it terminates completely if high pressure is measured and act as safety interlock which is a protective system requirement as part of its essential performance of APD Devices.

In reduced flow or no flow, each device allows for the extension of the estimated time to meet the prescription volume. Dialysate volume is the critical parameter in peritoneal dialysis and not flow rate.

The flow rate control does not affect the dialysate volume accuracy. Neither device changes the prescribed volume delivered to the patient.

Both devices continuously monitor the fluid pressure, fluid delivery to and from the patient temporarily stops if high pressure is measured, it resumes pumping fluid automatically as the pressure falls back into operating pressure ranges within the estimated exchange duration or otherwise alarms the patient to check fluid line resistance and then to resume treatment manually.

The fluid flow rate control algorithm is related with the continuous monitoring of fluid pressure and the principle of operation is similar in both devices regardless of different pumping technologies.

The Byonyks device utilizes a simple rotary peristaltic pump combined with a stepper motor driven valving system, the Fresenius Liberty Cycler uses two stepper motors driving mechanical plungers acting upon flexible fluid chambers in a cassette connected by check valves to move fluid. Basically, functioning as a diaphragm pump.

Rotary peristaltic pumps function by using rotating rollers to compress a flexible tube against a fixed casing or track. As the rollers rotate, they compress the tube or hose, creating a seal and moving

fluid through the pump. The pump's flow rate is controlled by adjusting the speed of the motor driving the rollers.

Diaphragm pumps function by using a flexible diaphragm to create suction and discharge pressure in a pumping chamber. As the diaphragm moves up, it creates a vacuum, which draws fluid into the chamber.

When the diaphragm moves down, it compresses the fluid, pushing it out of the chamber and through the discharge outlet. This process is repeated with each stroke of the diaphragm, resulting in a continuous flow of fluid.

Each of the above methods perform equivalently in terms of fluid flow and accuracy.

The safety mechanisms are similar for the two systems in that each device is equipped with an identical list of device safety alarms: over fluid pressure, over temperature and air-in-line, along with various warnings and alarms for machine-related issues such as low battery and proper placement of the disposable.

21 Non-Clinical and/or Clinical Tests Summary and conclusions 21 CFR 807.92(b)

The information provided in this submission, including design verification, risk management, electrical safety, electromagnetic compatibility (EMC), biocompatibility, and usability testing, demonstrates the Byonyks X-1 APD Cycler functions as intended and supports the determination of substantial equivalence to the predicate devices. Test results demonstrate that the differences between the proposed and the predicate devices do not raise any new concerns with regard to safety or effectiveness.

The Indications for Use, technological characteristics, design, and performance requirements of the Byonyks X-1 APD Cycler are substantially equivalent to those of the predicate devices.