



December 29, 2022

liberDi, Ltd  
% Wanda Carpinella  
Principle Regulatory Consultant  
Insight Medical Consulting, LLC  
7 Barrows Road  
Shrewsbury, MA 01545

Re: K220935

Trade/Device Name: Digital Dialysis Clinic - Intelligent Dialysis Assistant (IDA) & IDA Cartridge  
with Medical Supervision Portal and IDA Smartphone App

Regulation Number: 21 CFR 876.5630

Regulation Name: Peritoneal dialysis system and accessories

Regulatory Class: Class II

Product Code: FKX

Dated: March 30, 2022

Received: March 31, 2022

Dear Wanda Carpinella:

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

**Jade M. Noble -S**

for  
Gema Gonzalez, MS  
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

## Indications for Use

510(k) Number (if known)  
K220935

Device Name

Digital Dialysis Clinic - Intelligent Dialysis Assistant (IDA) & IDA Cartridge with Medical Supervision Portal and IDA Smartphone App

Indications for Use (Describe)

Intelligent Dialysis Assistant (IDA) is intended for automatic single exchange of dialysate solution exchanges in the treatment of adult renal failure patients undergoing peritoneal dialysis.

All therapies using the Intelligent Dialysis Assistant (IDA) must be prescribed and performed under the responsibility of a physician who is familiar and well informed about peritoneal dialysis. The patient prescription may include single or multiple exchanges, depending on the patient's need.

The IDA Cartridge is a single-use, sterile cartridge exclusively for use with the IDA. It is intended to interface the IDA with the Twin Bag Set (patient dialysis prescription) and the patient's peritoneal catheter.

The Medical Supervision Portal is intended for use by healthcare professionals to remotely communicate new or modified treatment parameters with compatible dialysis instruments and transfer completed treatment data to a central database to aid in the review, analysis, and evaluation of patients' historical treatment results. This Medical Supervision Portal is not intended to be a substitute for good clinical management practices, nor does its operation create decisions or treatment pathways.

The IDA Smartphone App is a software medical application intended for patients to review their treatment parameters and review and approve their dialysis prescription provided by the healthcare professional through the Medical Supervision Portal. The user is not intended to take clinical action based on the application output without consultation of a qualified healthcare professional.

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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