November 18, 2016

BELLOCO Srl  
% Barry Sall  
Principal Consultant  
PAREXEL Consulting, LLC  
195 West Street  
Waltham, MA 02451

Re: K160558  
Trade/Device Name: RAPIDO BLS HOLLOW-FIBRE DIALYZER  
RAPIDO BLS series: BLS 808; 812, 816, 819, 821  
(high flux fiber)  
Regulation Number: 21 CFR§ 876.5860  
Regulation Name: High Permeability Hemodialysis System  
Regulatory Class: II  
Product Code: KDI  
Dated: October 14, 2016  
Received: October 17, 2016

Dear Barry Sall:

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 Industry and Consumer Education 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" (21 CFR 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 Industry and Consumer Education 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,

Joyce M. Whang -S

for
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
Indications for Use

510(k) Number *(if known)*
K160558

Device Name
RAPIDO BLS HOLLOW-FIBRE DIALYZER
RAPIDO BLS series: BLS 808; 812, 816, 819, 821
(high flux fiber).

Indications for Use *(Describe)*
The 800 series RAPIDO BLS HOLLOW-FIBRE DIALYZERS are single-use devices intended for hemodialysis (HD), hemofiltration (HF), and hemodiafiltration (HDF) to treat conditions of acute or chronic renal failure when conservative therapy is judged to be inadequate. They are also indicated in the treatment of patients intoxicated with poisons or drugs.

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

- [x] 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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510(k) SUMMARY

SUBMITTER: Bellco Srl
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41037 Mirandola (MO), Italy

CONTACT PERSON: Giuseppe Tomasini
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DATE PREPARED: November 18, 2016

DEVICE TRADE NAME: RAPIDO BLS HOLLOW-FIBRE DIALYZER
RAPIDO BLS series: BLS 808; 812, 816, 819, 821 (high flux fiber).

COMMON NAME: hemofilter/dialyzer

CLASSIFICATION NAME: High Permeability Hemodialysis System, 21 CFR 876.5860

PREDICATE DEVICE(S): Xenium Dialyzer, Models 190 and 210
(K062079) Syntra 120, 160 (K002210) and the Polyflux6H (K051520)

DEVICE DESCRIPTION:
The above mentioned devices are dialyzers consisting of a cylindrical polycarbonate transparent body containing a bundle of microporous hollow fibers in highly-permeable polyethersulfone (Diapes® HF) secured to the ends by means of hot-melt polyurethane resin.

INDICATION FOR USE:
The 800 series RAPIDO BLS HOLLOW-FIBRE DIALYZERS are single-use devices intended for hemodialysis (HD), hemofiltration (HF) and hemodiafiltration (HDF) to treat conditions of acute or chronic renal failure when conservative therapy is judged to be inadequate. They are also indicated in the treatment of patients intoxicated with poisons or drugs.

TECHNOLOGICAL CHARACTERISTICS:
The design, operating principles and control mechanism are exactly the same for the Rapido BLS and the Xenium Dialyzer, Model 190, and 210 (K062079) predicate devices. The basic function of all above mentioned dialyzers is similar.

They share the same design, patient population, performance characteristics, technological characteristics and manufacturing processes. The RAPIDO BLS has exactly the same materials, manufacturing processes and biocompatibility of mentioned predicate devices. The basic function of all the above mentioned devices is the same for the indication in hemofiltration: the removal of excess fluid from patient's blood.

**NON CLINICAL TEST RESULTS:**

Applicable tests were carried out in accordance with the requirements of ISO 10993-1. Sterility, pyrogenicity, EtO residual and package integrity testing were also conducted. The results of this testing met established specifications.

**IN VITRO TEST RESULTS:**

*In vitro* test methods were carried out where applicable for providing the data necessary to demonstrate both the substantial equivalence with the predicate devices and also compliant with safety and effectiveness requirements. The device was aged and tested for: mechanical integrity, priming volume, pressure drop, ultrafiltration rate, sieving coefficient, hemolysis. The results of these tests met established specifications. For comparative purposes, the same testing, when applicable, was also conducted on the Xenium, Syntra and Polyflux 6H predicate devices. The shipping carton passed the basic testing and was still capable of providing adequate protection for further handling.

Data collected show that functional and biocompatibility parameters exhibited by the currently marketed Xenium, Syntra and Polyflux 6H apply to the RAPIDO BLS.

Device performance testing included:

1. Priming
2. Blood side pressure drop
3. Ultrafiltration rate
4. Sieving coefficient
5. Mechanical integrity
CONCLUSIONS:

The results on in vitro studies demonstrate the RAPIDO BLS performs in a manner substantially equivalent to the predicate devices. Biocompatibility studies demonstrate that the device is biocompatible according to its intended use. Additional testing has also demonstrates the effectiveness of production techniques to assure that the dialyzer is sterile and non-pyrogenic.