DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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March 18, 2016

Nikkiso Co., Ltd.
% Fumiaki Kanai, Ph.D.
President and CEO
MIC International
4-1-17 Hongo
Bunkyo-ku ,Tokyo 113-0033
Japan

Re: K152938
Trade/Device Name: DBB-06 Hemodialysis Delivery System
Regulation Number: 21 CFR§ 876.5860
Regulation Name: High Permeability Hemodialysis System
Regulatory Class: II
Product Code: KDI
Dated: February 15, 2016
Received: February 17, 2016

Dear Fumiaki Kanai,

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

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 below.

510(k) Number *(if known)*

K152938

Device Name

DBB-06 Hemodialysis Delivery System

Indications for Use *(Describe)*

The DBB-06 Hemodialysis Delivery System is indicated for hemodialysis prescribed by physicians for adult patients with acute and chronic renal failure, treated in hospitals and dialysis clinics by qualified operators. The DBB-06 Hemodialysis Delivery System is not indicated for pediatric patients. It is not for home use.

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)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Section 6- 510(k) Summary

a. Company name, address

Nikkiso Co., Ltd.
Medical Division
20-3, Ebisu 4-Chome, Shibuya-ku,
Tokyo 150-6022, Japan

b. Contact

Seiya Raijyu
General Manager
Quality Assurance Office

c. Date prepared

October 1, 2015

d. Name of device

Trade Name:	DBB-06 HEMODIALYSIS DELIVERY SYSTEM
Common Name:	High Permeability Hemodialysis System
Classification Name:	Dialyzer, High Permeability With or Without Sealed Dialysate System

e. Predicate devices

The DBB-06 HEMODIALYSIS DELIVERY SYSTEM is substantially equivalent to:

510(k):	K091978
Trade name:	DBB-06 Hemodialysis Delivery System
Product code:	KDI

510(k):	K083460
Trade name:	Dialog+ Hemodialysis System with Adimea Option
Product code:	KDI

f. Description of the device

The DBB-06 HEMODIALYSIS DELIVERY SYSTEM is composed of a hydraulic unit for the delivery of dialysate and extracorporeal blood circuitry. The permeate is heated and deaerated in the hydraulic section, which is then mixed with concentrate and fed into the dialyzer through the dialysate fluid feeder. The closed balancing system assures the amount of dialysate infused corresponds to the amount of dialysate extracted. The interior pressure of the dialyzer is controlled automatically by adjustment of the ultra filtration amount and UF rate by the dialyzer. Heparinization of the external circulating blood is accomplished with the heparin pump either by continuous or bolus injection before it is passed on to the dialyzer.

The DBB-06 HEMODIALYSIS DELIVERY SYSTEM uses both acetate dialysis and bicarbonate dialysis. Utilizing the various functions of the device, the conductivity and UF profile can be programmed. In addition, the device incorporates all functions necessary for double-needle dialysis as well as single-needle dialysis procedures. The hydraulic unit is cleaned and disinfected using selectable cleaning programs and is equipped with protective systems for patient safety and proper operation.

A Dialysis Dose Monitor (DDM) is a new optional accessory available with the DBB-06 (under application), which was not available in the predicate DBB-06 (K091978).

g. Indications for Use

The DBB-06 Hemodialysis Delivery System is indicated for hemodialysis prescribed by physicians for adult patients with acute and chronic renal failure, treated in hospitals and dialysis clinics by qualified operators. The DBB-06 Hemodialysis Delivery System is not indicated for pediatric patients. It is not for home use.

h. Statement of substantial equivalence

The DBB-06 HEMODIALYSIS DELIVERY SYSTEM (under application) was modified from the DBB-06 HEMODIALYSIS DELIVERY SYSTEM (K091978). The two devices are substantially equivalent and both have:

- the same Indications for Use
- use the same Operating Principle
- incorporate the same Basic System Design
- incorporate the same Materials

<u>New optional accessories</u>

<u>Dialysis Dose Monitor (DDM)</u>

A Dialysis Dose Monitor (DDM) is a new optional accessory available with the DBB-06 (under application), which was not available in the predicate DBB-06 (K091978).

The Dialysis Dose Monitor (DDM) is a measurement function which estimates the Kt/V value and Urea Reduction Ratio (URR) by optical measurement of the composition change in the spent dialysis fluid.

- DDM is a non-invasive measurement method. DDM does not influence treatment.
- DDM is a continuous measurement method.
- DDM does not require disposable items.
- DDM measurement starts automatically.
- Kt/V and URR are displayed on the screen as a graph.

The Dialysis Dose Monitor (DDM) of the DBB-06 (under application) and the Adimea (K083460) are identical in function and operate under the same principle of light absorption passing through the spent dialysis fluid.

The following is a comparison table between the Dialysis Dose Monitor (DDM) of the DBB-06 (under application) and the Adimea (K083460):

Table 1 DDM Comparison Table

Item	Dialog+ Hemodialysis System with Adimea Option (K083460)	Dialysis Dose Monitor (DDM) DBB-06 (under application)
Intended Use	It is used for estimating the Kt/V value and Urea Reduction Ratio (URR) by optical measurement of the composition change in the spent dialysis fluid.	Same
Technological Characteristics		
Principle of Kt/V and URR	The accessory functions and operates under the principles of light absorption through the spent dialysis fluid to calculate Kt/V and URR.	Same
Microprocessor control	Yes	Yes
Kt/V Accuracy		
Correlation Coefficient*[1]	0.93, 0.80	0.78
Error*[2]	Nonsystematic error 7%	Relative Error 6.26%

Note:

*[1] Correlation Coefficient was obtained by comparing Kt/V from UV absorption and measurement from blood. For Adimea two correlation coefficients were obtained for Study 1 and 2. See Section 22 Performance Testing-Clinical for details.

*[2] Measurement error in Kt/V values obtained from UV absorption relative to measurement by using blood. See Section 22 Performance Testing-Clinical for details.

Based on the technical characteristics, performance and failure simulation testing of the Dialysis Dose Monitor (DDM) of the DBB-06 (under application), NIKKISO CO., LTD. concluded that the Dialysis Dose Monitor (DDM) of the DBB-06 (under application) performed as well as and is substantially equivalent to the Adimea (K083460) and does not raise any new questions regarding safety or effectiveness.

i. Comparison table

Table 2 below compares the DBB-06 (under application) and the predicate DBB-06 (K091978). The two devices have the same Indications for Use, proportioning system, temperature control, alarm limits, bicarbonate and total conductivity range, flow rates, pressure monitoring and other relevant characteristics.

Table 2. Comparison table between the DBB-06 (under application) and the predicate DBB-06 (K091978)

Device Characteristics	PREDICATE	PROPOSED
	Nikkiso DBB-06 Hemodialysis Delivery System (K091978)	Nikkiso DBB-06 Hemodialysis Delivery System (under application)
Product Code	KDI	Same
Indications for Use	The DBB-06 Hemodialysis Delivery System is indicated for hemodialysis prescribed by physicians for adult patients with acute and chronic renal failure, treated in hospitals and dialysis clinics by qualified operators. The DBB-06 Hemodialysis Delivery System is not indicated for pediatric patients. It is not for home use.	Same
Proportioning system	Continuous volumetric dilution with duplex pump	Same
Temperature control (°C)	34 to 40	Same
Temperature alarm limit (°C)	Fixed: 33, 41 Auto: ±1 from set value*[1]	Same
Bicarbonate conductivity range (mS/cm)	2.30 to 7.00	Same
Total conductivity range (mS/cm)	12.5 to 15.5	Same
Flow (mL/min)	0, 300 to 800	Same
Transmembrane pressure (mmHg)	-100 to +500	Same
Sodium therapy	Yes, Profiled	Same
Ultrafiltration removal rate (L/h)	0.00; 0.10 to 4.00, Profiled UF	Same
PH monitor	None	Same
Bypass indicator	Visual	Same

Table 2. Comparison table between the DBB-06 (under application) and the predicate DBB-06 (K091978) (continued)

Device Characteristics	PREDICATE Nikkiso DBB-06 Hemodialysis Delivery System (K091978)	PROPOSED Nikkiso DBB-06 Hemodialysis Delivery System (under application)
BLOOD CIRCUIT		
Arterial pressure (mmHg)	-300 to +300	Same
Venous pressure (mmHg)	-200 to +500	Same
Blood pump range (mL/min)	40 to 600	Same
Heparin pump range (mL/h)	0.0 to 9.9 (10, 20, 30 mL syringe)	Same
Disinfection	Chemical, thermo-chemical, hot rinse	Same
Display type	LCD, 12.1" color, SVGA	Same
DISPLAY PARAMETERS		
Dialysate pressure	Yes	Same
Transmembrane pressure	Yes	Same
Bicarbonate conductivity	Yes*[2]	Same
Total conductivity	Yes	Same
Flow rate	Yes	Same
Elapsed time	Yes	Same
Remaining time	Yes	Same
Complete time	Yes	Same
Kt/V ratio calculation display	Yes	Same
Dialysis Dose Monitor (DDM)	No	Yes
Blood pressure value history	Numeric or Graphical	Same
Blood volume	Yes	Same
MICROPROCESSOR		
Type	3 microprocessor system, TX1941AF Toshiba, 32 bit	Same
Storage	Treatment data	Same
Interface	Built-in RS-232 for technician, Optional TCP/IP for network	Same
Loss of water alarm	Yes	Same
OTHER SPECIFICATIONS		
Single needle Click-Clack	Yes	Same
Arterial clamp for use during Single needle Click-Clack	Yes	Same
Bicarbonate concentrate type	Liquid or Dry Powder	Same
Built in BP monitoring	Yes	Same
Isolation UF	Yes	Same
Online UF control test	Yes, Continuously*[3]	Same
Built in Blood Volume Monitor (BVM)	Yes	Same

Note:

*[1] The dialysate temperature alarm limit is set to ±1°C from the temperature target value automatically. The alarm window ±1°C can be changed from 0 to ±5°C.

*[2] The maximum concentrate deviation alarm limit is set at ±3%.

*[3] Specification of online UF control test.

j. Conclusion

Based on the above discussion, enclosed sections regarding substantial equivalence to the predicate devices, and the substantial equivalence of Dialysis Dose Monitor (DDM) of the DBB-06 (under application) to the Adimea (K083460), NIKKISO CO., LTD. concludes that the DBB-06 (under application) is substantially equivalent to the predicate DBB-06 (K091978).