K130851

SECTION 5.0

JAN - 9 2014

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
for the *CASCADE*™ Hemodialysis/Apheresis Catheter (21 CFR 807.92)

(See Following Page)

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
(21 CFR 807.92)
for *CASCADE*™ Hemodialysis/Apheresis Catheter

SUBMITTER:
Health Line International Corporation
803 N. 1250 W. – STE 1
Centerville, Utah 84014

ESTABLISHMENT REGISTRATION NUMBER:
3006097687

CONTACT:
Nola Benstog
QA/RA Director
Telephone: 801-773-7798 X 107
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Email: nbenstog@hlic.net

DATE PREPARED:
March 21, 2013

NAME OF MEDICAL DEVICE:

Proprietary Name:	*CASCADE*™ Hemodialysis/Apheresis Catheter
Regulation Name:	Blood access device and accessories
Common/Usual Name:	Hemodialysis Catheter, Implanted

DEVICE CLASSIFICATION:

Classification Panel:	Gastroenterology / Urology
Regulatory Class:	Class III
Product Code:	MSD
Regulation Number:	21 CFR 876.5540

PREDICATE DEVICE:

Proprietary Name:	***Hemo-Cath® (K113487)***
Regulation Name:	Blood access device and accessories
Common/Usual Name:	Hemodialysis Catheter, Implanted
Classification Panel:	Gastroenterology / Urology
Regulatory Class:	Class III
Product Code:	MSD
Regulation Number:	21 CFR 876.5540

DEVICE DESCRIPTION:

The *CASCADE*™ Hemodialysis/Apheresis Catheter is a family of percutaneously inserted catheters designed to perform Hemodialysis therapy and Apheresis. The catheters are manufactured from medical grade radiopaque silicone material, which provides increased patient comfort while offering excellent biocompatibility. The *CASCADE*™ Hemodialysis/Apheresis Catheter Kit includes a catheter and introduction components. The catheter is supplied sterile and non-pyrogenic in a variety of kit configurations.

The *CASCADE*™ Hemodialysis/Apheresis Catheter is indicated for dwell times greater than 30 days. The *CASCADE*™ Hemodialysis/Apheresis Catheter product line has catheters in 12.5 Fr dual lumen sizes. Catheters range from approximately 13 - 55 cm long and are offered in straight or curved catheter configurations with cuffs for long-term implantation. The catheters are attached to an injection-molded silicone hub that has a suture wing and extension legs with Luer lock fittings for access attachment.

INTENDED USE:

The *CASCADE*™ Hemodialysis/Apheresis Catheter is intended for use in attaining long-term vascular access for Hemodialysis therapy and Apheresis. It may be inserted percutaneously and is primarily placed in the internal jugular vein. Alternate insertion sites include the subclavian vein and femoral vein, as required.

INDICATIONS FOR USE:

- The *CASCADE*™ Hemodialysis/Apheresis Catheter is indicated for use in attaining Long-Term (greater than 30 days) vascular access for Hemodialysis therapy and Apheresis.
- It may be inserted percutaneously and is primarily placed in the internal jugular vein of an adult patient.
- Alternate insertion sites include subclavian vein as required.
- Catheters greater than 40 cm are intended for femoral vein insertion.
- The curved *CASCADE*™ Hemodialysis/Apheresis Catheter is intended for internal jugular vein insertion.

TECHNOLOGICAL COMPARISON TO PREDICATE DEVICES:

New device is compared to Marketed Device? Yes. It is compared to a legally marketed predicate device.

Does the new device have the same indication statements? Yes, the *CASCADE*™ Hemodialysis/Apheresis Catheter indications are substantially equivalent to the predicate device. Differences include limiting the access to long term (removal of temporary access) and removal of hemoperfusion. Additionally, Health Line includes a statement that the curved catheter is intended for internal jugular vein insertion (consistent with the primary placement site).

Do the differences alter the intended therapeutic/diagnostic/etc. effect (i.e. deciding may consider impact on safety and effectiveness)? No, the differences do not alter the intended effect of the device.

Does the new device have the same technological characteristics, e.g. design, material, etc.? Yes. The *CASCADE*™ Hemodialysis/Apheresis Catheter technological characteristics are identical to the Medcomp *Hemo-Cath*® (K113487). The basic fundamental technological characteristics of the device have not changed. There may be minor variations in the size of lumen. Additionally, the *CASCADE*™ Hemodialysis/Apheresis Catheter is made from a silicone material, which is identical to Medcomp *Hemo-Cath*® (K113487). These differences have no negative impact on the device performance, safety or efficacy.

Could the new characteristics affect safety or effectiveness? No.

Do the new characteristics raise new types of safety and effectiveness questions? No. There are no new types of safety and effectiveness questions.

Do accepted scientific methods exist for assessing effects of the new characteristics? Yes.

The FDA's Draft Guidance, *Class II Special Controls Guidance Document: Implanted Blood Access Devices for Hemodialysis*, dated June 28, 2013 was used as a guide to determine the appropriate methods for evaluating the device's performance characteristics.

Sterilization requirements of ISO 11135:2007, Sterilization of Health Care Products - Requirements for Validation and Routine Control -- Ethylene Oxide Sterilization.

Biocompatibility requirements according to ISO-10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing. Test profiles for externally communicating, circulating blood, permanent contact devices will be met.

These and other standards were used to determine the appropriate methods for evaluating the device's performance.

Are performance data available to assess effects of new characteristics? Yes. Verification testing was performed according to protocols based on the above-referenced guidance document recommendations and additional standards.

Do performance data demonstrate equivalence? Yes. Performance data gathered in design verification testing demonstrated that the *CASCADE*™ Hemodialysis/Apheresis Catheter is substantially equivalent to the noted predicate device.

Additionally, consideration was given to the Draft Guidance for Industry and Food and Drug Administration Staff, Class II Special Controls Guidance Document: Implanted Blood Access Devices for Hemodialysis issued on June 20, 2012 throughout this submission, as it pertains to the safety and effectiveness of the device.

CONCLUSION

The *CASCADE*™ Hemodialysis/Apheresis Catheter met all established acceptance criteria for performance testing and design verification testing. This testing demonstrated that the *CASCADE*™ Hemodialysis/Apheresis Catheter is safe and effective for its intended use, and based on FDA's decision tree is substantially equivalent to the following predicate device: Medcomp Hemo-Cath (K113487).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 9, 2014

Nola Bentsog
QA/RA Director
Health Line International Corporation
803 N. 1250 West - Suite I
Centerville, UT 89014

Re: K130851
Trade/Device Name: CASCADE™ Hemodialysis/Apheresis Catheter
Regulation Number: 21 CFR 876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: III
Product Code: MSD
Dated: November 11, 2013
Received: November 13, 2014

Dear Nola Bentsog,

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. However, you are responsible to determine that the medical devices you use as components in the [kit/tray] have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit/tray. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and 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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Herbert P. Lerner -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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K130851

Device Name
CASCADE™ Hemodialysis/Apheresis Catheter

Indications for Use *(Describe)*

Indications For Use:

- The CASCADE™ Hemodialysis/Apheresis Catheter is indicated for use in attaining Long-Term (greater than 30 days) vascular access for Hemodialysis therapy and Apheresis.
- It may be inserted percutaneously and is primarily placed in the internal jugular vein of an adult patient.
- Alternate insertion sites include subclavian vein as required.
- Catheters greater than 40 cm are intended for femoral vein insertion.
- The curved CASCADE™ Hemodialysis/Apheresis Catheter is intended for internal jugular vein insertion.

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)*

Herbert P. Lerner -S
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