AUG 2 3 2011

5. 510(K) SUMMARY

DEKA Tension-Activated Clamp (TAC) Device

Applicant:

DEKA Research & Development Corporation
340 Commercial Street
Manchester, NH 03101-1129

Contact Person: Roger Leroux
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Date Prepared: December 18, 2009

Device:

Proprietary Name:	DEKA TAC Device
Common/Usual Name:	Automatic Blood Tubing Clamp
Classification:	Class II; 21 CFR 876.5820; Hemodialysis system and accessories; Product Code: FIG

Device Description:

The DEKA TAC is a multiple-use safety device designed to be used during hemodialysis treatments. The device mounts near the fistula needle on the patient and is designed to clip over the fistula needle tubing. It is designed to occlude the blood flow in the venous blood line should the blood circuit tubing get tangled or tugged or the fistula needle tubing rotated beyond a threshold limit. It will automatically occlude the line once tension, exceeding a pre-established value, is presented to the tubing with a threshold lower than what is required to extract the needle. This occlusion will prevent blood loss should the force on the tubing be great enough to cause the needle to be partially or fully removed from the patient.

Predicate Device:

The DEKA TAC is substantially equivalent (i.e., has the same intended use and similar technological characteristics) to the Rocky Mt. Research Automatic Tubing Clamp System (K914459) and the Medivice SidePort Pinch Clamp Device (K010888). DEKA bases this claim of substantial equivalence on intended use and in recognition that the differences in technological characteristics do not affect the safety and effectiveness of the device.

The following table illustrates the equivalence between the DEKA TAC and its predicates.

Device	Rocky Mt. Research Automatic Tubing Clamp System (K914459)	DEKA TAC	Medivice SidePort™ Pinch Clamp Device (K010888)
Technical Characteristic			
Summary	The Rocky Mountain Research Automatic Tubing Clamp is an active device that monitors blood flow in a cardiopulmonary bypass line for air bubbles and low or retrograde flow. Upon detection of one of these conditions, the device automatically obstructs the flow of the fluid in the soft tubing by closing its accompanying external tubing clamps and alerting the user to the event.	The DEKA Tension Activated Clamp (TAC) is a passive device intended to externally obstruct the flow of fluid in a soft tube during hemodialysis. It is triggered when a force is applied to the hemodialysis blood tubing line.	The Medivice SidePort Pinch Clamp is a passive device that permits a user to externally obstruct the flow of fluid in a soft tube. The Pinch Clamp is commonly found on hemodialysis blood tubing sets and used by caregivers and home patients alike.
Gross Dimensions	Control Box: 11" depth, 10" width, 5" height Transducer: 0.75" depth, 2" width, 1.3" height	3" length, 1.2" width, 0.71" height	Approximately 1" in all directions
Weight	Control Box: 10 lbs. Arterial and Venous clamps: 1.0 lb each. Transducer: 0.5 lbs.	Less than 29 grams	Unspecified
Tubing Compatibility	For use with 3/8" or 1/2" ID x 3/32" wall tubing	5.00-5.25 mm OD	2.0-7.3 mm OD
Materials	ABS, aluminum, polyurethane, stainless steel, brass	Polypropylene (skin contact), aluminum, government black	Acetal or Nylon
Electricity	Required	Not Required	Not Required
Actuation Mechanism	Pressurized gas based on Air and Flow sensors	Cocked spring actuated by tension in the tubing line	Manual

Device	Rocky Mt. Research Automatic Tubing Clamp System (K914459)	DEKA TAC	Medivice SidePort™ Pinch Clamp Device (K010888)
Technical Characteristic			
Bubble Detection Sensitivity	> 0.35 ul @ 2 l/min	Not applicable	Not applicable
Reverse Flow Sensitivity	< 0.5 liters per minute + 0.25 lpm	Not applicable	Not applicable
Transducer Energy	Continuous 2.5 MHZ, 0.03 Watts	Not applicable	Not applicable
External Indicators	Power, air bubble detected, reverse flow detected, arterial clamp status, venous clamp status, gas power failure	None. Relies on accompanying hemodialysis instrument for indication of flow stoppage.	None
External Controls	Power switch, arterial clamp switch, venous clamp switch	None	None
Alarms	3.8 kHz continuous alarm on reverse flow, air detected or clamp fault	None. Relies on accompanying hemodialysis instrument for indication of flow stoppage.	None
Response Time	Unspecified	Less than 0.5 seconds	Not applicable

Indications for Use:

The DEKA TAC is an automatic tubing clamp device intended for use in a clinical facility as an accessory to a hemodialysis blood circuit to automatically clamp the blood flow in the hemodialysis circuit upon detection of tension in the venous access line in excess of a pre-defined threshold value. The DEKA TAC may be mounted on, or removed from, already assembled hemodialysis blood circuits

Test Results

Results of in-vitro testing and biocompatibility assessments demonstrate that the DEKA TAC presents no new issues of safety or technology to the predicate device(s) and, as such, is substantially equivalent to the predicate device.

The non-clinical testing intended to support a claim of substantial equivalence is summarized in DKBF-00515-001 starting on page 126 of the original 510(k) submission. In this summary report, the key testing intended to support the claim of substantial equivalence is as follows:

- The DEKA TAC device has the ability to interface with standard tubing by attaching externally to standard 5mm outer diameter hemodialysis fistula needle sets. This was demonstrated by conducting performance tests using the following needle sets: Baxter Seraflo, Nipro SafeTouch II and Medisystem Readyset. Reference section 4.1 of DKBF-00515-001 page 133.

- The DEKA TAC has the ability to automatically activate based on external conditions. This is shown in The Actuation Forces Testing Section of the original 510 (k) submission. This section provides the results of the device testing with external forces applied to test force threshold. Reference section 4.2 of DKBF-00515-001 page 134.

- The DEKA TAC has the ability to fully occlude fluid flow. This is evidenced by the testing of the effectiveness of the clamp at stopping the flow in the tubing as well as the leak rate of a closed clamp. Reference section 4.3 of DKBF-00515-001 page 139.

Summary and Conclusions

Based on the information presented above, DEKA has demonstrated that the DEKA TAC is substantially equivalent to the cited predicate devices.

The DEKA TAC presents no new issues of safety or technology to the predicate device and, as such, is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Mr. Roger A. Leroux
Director of Regulatory and Clinical Affairs
DEKA Research & Development Corp.
340 Commercial Street
MANCHESTER NH 03101

AUG 23 2011

Re: K093915
Trade/Device Name: DEKA Tension-Activated Clamp (TAC) Device
Regulation Number: 21 CFR§ 876.5820
Regulation Name: Hemodialysis system and accessories
Regulatory Class: II
Product Code: FIG
Dated: June 28, 2011
Received: June 29, 2011

Dear Mr. Leroux:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. INDICATIONS FOR USE

510(k) Number (if known): K093915

Device Name: DEKA Tension-Activated Clamp (TAC) Device

Indications for Use:

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use_____ (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

(Division Sign-Off) Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Reproductive, Gastro-Renal, and Urological Devices

510(k) Number K093915

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