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FEB - 3 2010

MEDEFIL, INC.



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510(k) SUMMARY

MEDEFIL'S HEPARIN I. V. FLUSH SYRINGE

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

- 1. Reason for 510(k): Introduction of a terminally sterilized product
- 2. Name of Device:
 - Classification Name Catheter Intravascular, Small Volume
 - Common Name Heparin I. V. Flush Syringe, USP.
 - Proprietary Name Medefil's Heparin I. V. Flush Syringe
 - 1 Unit/mL or 10 Units/mL or 100 Units/mL
- 3. Classification:
 - Name/Class 21 CFR 880.5200
 - Intravascular, Short Term / Class II
 - Panel General Hospital
 - Product Code NZW
- 4. Date Summary was prepared: February 1, 2010
- 5. Establishment Registration Number: 1423982
- 6. Submitter's Name and Address: Medefil, Inc.
250 Windy Point Drive,
Glendale Heights, Illinois 60139
- 7. Contact Person and telephone number: Pradeep Aggarwal
Telephone: (630) 682 - 4600
- 8. Manufacturing and sterilization facilities: Medefil, Inc.
250 Windy Point Drive
Glendale Heights, Illinois 60139

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9. Substantial Equivalence:

The intended use and principal technological characteristics of the DEVICE are substantially equivalent to the legally marketed predicate device listed below:

Medefil, Inc.
Heparin I. V. Flush Syringe
(K020996)

10. Device Description:

The Heparin I. V. Flush Syringe (the DEVICE) is a single dose, disposable, sterile, plastic pre-filled syringe. The DEVICE consists of a hypodermic syringe barrel, stopper plunger, plunger rod, luer lock (LL) tip cap and Heparin Lock Flush Solution, USP (1 Unit/mL or 10 Units/mL or 100 Units/mL in 0.9% Sodium Chloride), which meets the requirements set forth in the current USP Heparin Lock Flush Solution monograph. Two different sizes (6 mL, 12 mL) of hypodermic syringes will be utilized in packaging. The DEVICE will be marketed in the following dosage forms:

1 mL fill in 6 mL Syringe LL
2 mL fill in 6 mL Syringe LL
2.5 ml fill in 6 ml Syringe LL
3 mL fill in 6 mL Syringe LL
3 mL fill in 12 mL Syringe LL
5 mL fill in 6 mL Syringe LL
5 mL fill in 12 mL Syringe LL
10 mL fill in 12 mL Syringe LL

The hypodermic syringe is transparent. The barrel of the DEVICE is the reservoir for the product and will be overfilled during manufacturing process. The plunger and plunger rod are the only two moving parts of the device. The flush solution is delivered by pressing down on the plunger rod, resulting in the expulsion of the fluid from the luer tip.

The DEVICE will be filled using fully automated syringe filling machine utilizing non - sterile components. The components of the DEVICE (hypodermic syringe, tip cap and (Heparin Lock Flush Solution, USP) will be sterilized using steam in a terminal sterilizer after the syringe barrel is filled with Heparin Lock Flush Solution and sealed with Tip Cap and Plunger Stopper.

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11. Intended Use:

Same Intended Use as the Predicate Device.

For use to maintain the patency of in-dwelling intravenous vascular access device (IVAD).

12. Packaging:

The DEVICE provided is individually packaged in a plastic pouch (dust cover). There are thirty (30), sixty (60) or one hundred twenty (120) individually packaged DEVICES in a dispensing box. Nine hundred sixty syringes (thirty two boxes of 30's, or sixteen boxes of 60's or eight boxes of 120's) individually packed devices will be packed in a card board master carton.

The DEVICE shall be pyrogen free per the LAL test method for bacterial endotoxin.

13. Technological Characters:

The Medefil's Heparin I. V. Flush Syringe Device is similar to the legally marketed predicate device except the differences are:

- a) The DEVICE will be manufactured using terminal sterilization process using steam where as the predicate device was manufactured using aseptic technique. The DEVICE will be filled and sealed in syringe barrels and then it will be subjected to steam sterilization where as for the predicate device sterile solution was filled in pre sterilized syringe barrels and this leads to increased sterility assurance
- b) To accommodate steam sterilization, the polypropylene used in the DEVICE was changed to one which will be able to withstand steam sterilization where as the polypropylene used in the predicate device was only able to withstand Gamma Radiation.

14. Performance Data:

Three types of tests – physical (dimensional), mechanical, and compatibility tests - were conducted. The dimensional and mechanical tests were conducted to demonstrate that the DEVICE meets the requirements set forth in the engineering drawings and that it performed comparably to the substantially equivalent device, thereby not affecting safety or effectiveness. These tests are done to assure the integrity of the container closure system. The terminally sterilized Heparin I. V. Flush Syringes were put through seal integrity tests (dye ingress test and microbial ingress test). The syringes tested were filled with product, sealed, steam sterilized using steam – air mixture (SAM) process, inspected, labeled and packaged for dye leak testing. The microbial ingress testing was performed by filling with Tryptic Soy Broth and tested for microbial ingress using vacuum method.

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The polypropylene resin as well as various color tip caps in the DEVICE is intended for components destined for subsequent steam sterilization. The polypropylene was tested for Biological Reactivity Tests In Vitro and In Vivo. The polypropylene was found to meet the requirements of a USP Class VI plastic. Similarly polypropylene and tip caps are also not cytotoxic in nature.

The stability testing was performed on Heparin I. V. Flush Syringes after terminal sterilization, per USP monograph Heparin Lock Flush Solution, both at accelerated temperature and real time temperature to demonstrate that the new syringe material and the sterilization process is compatible with the USP Heparin Lock Flush Solution thereby supporting the claim that the change in fluid container material does not raise new types of safety and effectiveness questions

15. Clinical Data:

Heparin I. V. Flush Syringe, 100 Units/mL did not result in any hemolysis as measured by quantitating free hemoglobin in plasma and LDH levels. Also there was no change in osmolality. The study showed that dilution of heparin in whole blood did not result in any measurable changes in various markers of hemolysis.

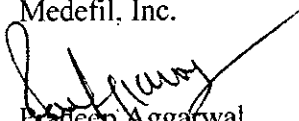
16. Conclusion:

The DEVICE is safe and effective. The new characteristic does not affect safety and effectiveness of the DEVICE and the DEVICE is substantially equivalent to its legally marketed predicate device. The changes (change in polypropylene and terminal sterilization) do not affect the safety or effectiveness because the systems and processes have been validated and verified to yield a product that fits its intended use. The terminal sterilization process has decreased any risk for contamination as the sterile processes are enhanced. Biocompatibility of polypropylene is not a concern because it has been tested and it meets the requirements of USP Class VI plastic. The tests also show that the DEVICE is safe and effective, the new characteristics DO NOT adversely affect the safety and effectiveness of the DEVICE, and the DEVICE is substantially equivalent to its legally marketed predicate device.

17. Certification:

I certify that, in my capacity as President & CEO of Medefil, Inc., I believe to the best of my knowledge that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

Sincerely
Medefil, Inc.


Pradeep Aggarwal
President & CEO



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

FEB - 3 2010

Mr. Pradeep Aggarwal
President and Chief Executive Officer
Medefil, Incorporated
250 Windy Point Drive
Glendale Heights, Illinois 60139

Re: K092491
Trade/Device Name: Heparin I.V. Flush Syringe
Regulation Number: 21CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: II
Product Code: NZW
Dated: January 25, 2010
Received: January 26, 2010

Dear Mr. Aggarwal:

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.

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,



Anthony D. Watson, B.S., M.S., M.B.A.
Director

Division of Anesthesiology, General Hospital,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use

510(k) Number (if known): K092491

Device Name: HEPARIN I. V. FLUSH SYRINGE

Products in 0.9% Sodium Chloride

| Model Number | Concentration | Fill Volume | Model Number | Concentration | Fill Volume |
|--------------|---------------|----------------------|--------------|---------------|----------------------|
| MIH-4421 | 1 Unit/mL | 1 mL in 6 mL Syringe | MIH-4422 | 1 Unit/mL | 2 mL in 6 mL Syringe |
| MIH-4452 | 1 Unit/mL | 2.5 mL in 6 mL Syr. | MIH-4423 | 1 Unit/mL | 3 mL in 6 mL Syringe |
| MIH-4425 | 1 Unit/mL | 5 mL in 6 mL Syringe | MIH-4433 | 1 Unit/mL | 3 mL in 12 mL Syr. |
| MIH-4435 | 1 Unit/mL | 5 mL in 12 mL Syr. | MIH-4430 | 1 Unit/mL | 10 mL in 12 mL Syr. |
| MIH-2221 | 10 Units/mL | 1 mL in 6 mL Syringe | MIH-2222 | 10 Units/mL | 2 mL in 6 mL Syringe |
| MIH-2252 | 10 Units/mL | 2.5 mL in 6 mL Syr. | MIH-2223 | 10 Units/mL | 3 mL in 6 mL Syringe |
| MIH-2225 | 10 Units/mL | 5 mL in 6 mL Syringe | MIH-2233 | 10 Units/mL | 3 mL in 12 mL Syr. |
| MIH-2235 | 10 Units/mL | 5 mL in 12 mL Syr. | MIH-2230 | 10 Units/mL | 10 mL in 12 mL Syr. |
| MIH-3321 | 100 Units/mL | 1 mL in 6 mL Syringe | MIH-3322 | 100 Units/mL | 2 mL in 6 mL Syringe |
| MIH-3352 | 100 Units/mL | 2.5 mL in 6 mL Syr. | MIH-3323 | 100 Units/mL | 3 mL in 6 mL Syringe |
| MIH-3325 | 100 Units/mL | 5 mL in 6 mL Syringe | MIH-3333 | 100 Units/mL | 3 mL in 12 mL Syr. |
| MIH-3335 | 100 Units/mL | 5 mL in 12 mL Syr. | MIH-3330 | 100 Units/mL | 10 mL in 12 mL Syr. |

Indications For Use:

FOR USE TO MAINTAIN THE PATENCY OF IN-DWELLING INTRAVENOUS VASCULAR ACCESS DEVICES (IVAD)

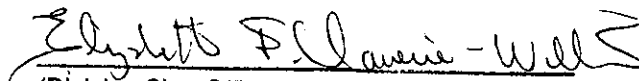
Prescription Use (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K092491