K093182

GRIFOLS	TECHNICAL EVALUATION DOCUMENTATION	# Document: TED-SET GRI-FILL 3.0 6 to 1 -05

SECTION 5 – SET GRI-FILL 3.0 6-to-1: 510(k) SUMMARY

JAN 27 2010

DATE OF SUBMISSION: 2009-09-24

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DEVICE TRADE NAME: SET GRI-FILL 3.0 6 to 1
COMMON NAME: I.V. FLUID TRANSFER SETS
CLASSIFICATION NAME: I.V. FLUID TRANSFER SETS (21 CFR 880.5440)

PREDICATE DEVICE(S):

QUICKPIN (Laboratorios Grifols – K082752)
FLEBOSET MULTIPLE (Laboratorios Grifols – K040456)

DEVICE DESCRIPTION:

Fluid transfer set consisting of PVC tubing linking 6 mini-spikes to be used in conjunction with SETS GRI-FILL 3.0 1 Way or 2 Way transfer sets through which the same substance from up to 6 rubber-stoppered glass vials may be delivered into a final IV container. It is equipped with a 0.2 micron hydrophobic air-filter that minimizes the formation of aerosols when preparing and dispensing the source substances. The spike on each line facilitates easy puncture of thick rubber stoppers of small diameter. The device provides fast fluid addition and extraction due to the large surface area of the air-filter that quickly equalizes pressures.

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INTENDED USE:

SET GRI-FILL 3.0 6 to 1 is a fluid transfer set to be used in conjunction with SETS GRI-FILL 3.0 1 WAY or 2 WAY through which the same substance from up to 6 rubber-stoppered glass vials may be delivered into a final IV container.

INDICATIONS FOR USE (as stated in the Statement provided in Section 4):

SET GRI-FILL 3.0 6 TO 1 is an ancillary device used as a fluid pathway in conjunction with the Gri-fill 3.0 Pharmacy Compounder and associated 1 way or 2 way transfer sets through which the same substance from up to 6 rubber-stoppered glass vials may be delivered into a final IV container. Equipped with a spike on each line and a 0.2 μm hydrophobic air-filter, it minimizes the formation of aerosols when preparing / dispensing the source substances. Facilitates easy puncture of thick rubber stoppers of small diameter. Provides fast fluid addition and extraction due to the large surface area of the air-filter.

This device should not be used with lipids, suspensions or solutions that are incompatible with PVC with DEHP plasticizer. Substances that are known to show incompatibility include, but are not limited to, Paclitaxel, Docetaxel, Etoposide, Carmustine, Propofol, Nitroglycerin, Isosorbide Dinitrate and Diazepam. For information concerning compatibility of substances, please consult the information provided with the substance.

This device is intended to be used by trained healthcare personnel. It is restricted to sale by or on the order of a physician.

SUMMARY OF COMPARISON WITH PREDICATE DEVICE:

In the establishment of substantial equivalence, SET GRI-FILL 3.0 6 to 1 is compared with another vial access device (QUICKPIN) and with IV fluid transfer sets (FLEBOSET MULTIPLE) both previously marketed by Laboratorios Grifols.

As described in Section 12 of this submission, the design, features, technological characteristics, mechanical specifications and bench performance of the proposed device have been compared in detail with those of the predicate devices.

On the basis of this data, we believe that the new 6 to 1 device consists of a combination of the predicate devices incorporating small dimension spikes equivalent to the Quickpin on a multiple path fluid transfer set similar to the Fleboset Multiple. Fluid transfer tubing material on the new device is identical to the fluid transfer tubing material of the predicate transfer set. Differences that may be highlighted between the new and predicate devices include the configuration of the output connectors. All differences have been addressed in the different bench tests performed on the proposed device and are discussed further in Section 12 of this submission.

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SUMMARY DISCUSSION OF NON-CLINICAL DATA:

All materials used in the construction of SET GRI-FILL 3.0 6 to 1 have been subject to chemical and biological testing in accordance with the applicable requirements taking account of its intended use. Functional laboratory bench testing performed in foreseeable operating conditions showed correct operation of the device as per its intended use.

CONCLUSIONS:

We believe the intended use, the indications for use, the functionality and the operation of the SET GRI-FILL 3.0 6 to 1 combines the indications for use, functionality and operation of the mentioned predicate devices QUICKPIN and FLEBOSET MULTIPLE. Technological differences including the different output connector configuration on the transfer set have been addressed and verified by bench-testing to have no adverse influence on the safety and performance of the proposed device. Hence, substantial equivalence of SET GRI-FILL 3.0 6 to 1 with the legally marketed predicate devices may be established.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Document Control Room –WO66-G609
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JAN 27 2010

Re: K093182
Trade/Device Name: Set Gri-Fill 3.0 6 to 1
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: LHI
Dated: December 18, 2009
Received: December 24, 2009

Dear Mr. Gascón:

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/cdrh/mdr/ 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

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

Enclosure

Indications for Use

510(k) Number (if known): **K093182**

Device Name: SET GRI-FILL 3.0 6 TO 1

Indications For Use:

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Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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

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