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GRIFOLS	TECHNICAL EVALUATION DOCUMENTATION	# Document: TED-SETS GRI-FILL 3.0-01

SECTION 1 – SETS GRI-FILL 3.0: 510(k) SUMMARY

DATE OF SUBMISSION: 2004-11-30

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

PREDICATE DEVICE: SETS GRI-FILL 2.0 1WAY / 2WAY / LUER (K033682)
FLEBOSET MULTIPLE (K040456)

DEVICE DESCRIPTION:

SETS GRI-FILL 3.0 are fluid transfer sets for use with the GRI-FILL 3.0 pharmacy compounding device in order to compound or mix different multi-ingredient solutions and to channel them into a final suitable IV container. The set is a disposable component of the compounding device. The 1WAY / 2WAY models are made up of a syringe, a distributor, tubing to channel the fluid and a waste/residue bag. Sets are available for 1 or 2 source substances. Also a Luer female – female adapter is available as an accessory to the 1 or 2 way transfer sets. The MULTIPLE model is also used as an accessory with the 1WAY / 2WAY sets for channeling the same solution from up to six (6) source containers delivering them into a final IV container. It is made up of connectors and tubing to enable interconnection of the different source containers.

INTENDED USE:

SETS GRI-FILL 3.0 1 WAY and 2 WAYS are disposable components of the GRI-FILL 3.0 pharmacy compounding system used to provide a fluid pathway through which one or two source substances are channeled to an IV container or syringe. SETS GRI-FILL 3.0 MULTIPLE are ancillary devices connected to SETS GRI-FILL 3.0 1 WAY or 2 WAYS used to provide a fluid pathway through which the same substance in up to 6 source containers may be delivered into a final IV container. The device is NOT intended to be connected directly to the patient.

SUMMARY OF COMPARISON WITH PREDICATE DEVICE:

In the establishment of substantial equivalence, SETS GRI-FILL 3.0 are compared with other transfer sets used in pharmacy compounding.

The following table summarizes the similarities of the principal technological characteristics and features of both predicate and new devices.

#	Characteristic / Feature	PROPOSED DEVICE	PREDICATE DEVICES	
		SETS GRI-FILL 3.0	SETS GRI-FILL 2.0	FLEBOSET MULTIPLE
1.	Intended use / Claims	SETS GRI-FILL 3.0 1 WAY and 2 WAYS are disposable components of the GRI-FILL 3.0 pharmacy compounding system used to provide a fluid pathway through which one or two source substances are channeled to an IV container or syringe. SETS GRI-FILL 3.0 MULTIPLE are ancillary devices connected to SETS GRI-FILL 3.0 1 WAY or 2 WAYS used to provide a fluid pathway through which the same substance in up to 6 source containers may be delivered into a final IV container. The device is NOT intended to be connected directly to the patient.	SETS GRI-FILL 2.0 are disposable components of the GRI-FILL 2.0 pharmacy compounding system used to provide a fluid pathway through which 1 or more source solutions are delivered into a single final solution. The device is NOT intended to be connected directly to the patient.	FLEBOSET MULTIPLE is an ancillary device used as fluid pathway through which substances from 6 glass source flasks containing the same solution may be continuously delivered for: (a) Pharmacy compounding, when used in conjunction with the GRI-FILL 2.0 pharmacy compounding device and associated transfer sets, and (b) I.V. administration, when used in conjunction with a gravity or pump infusion set to channel the solution from the source containers to the infusion set. The device should not be used with lipids.
2.	Technological features: - Sterilization - Direct patient hook-up	 Ethylene Oxide NO	 Ethylene Oxide NO	 Ethylene Oxide NO – Intended for use with the pharmacy compounding device or INDIRECT - May be used on-line with patient, upstream of the gravity or pump administration sets.
	- Source	1(1WAY Set), 2 (2WAY Set),	1 (1WAYSet) or 2 (2WAY	6

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GRIFOLS	TECHNICAL EVALUATION DOCUMENTATION	# Document: TED-SETS GRI-FILL 3.0-01

SECTION 1 – SETS GRI-FILL 3.0: 510(k) SUMMARY

#	Characteristic / Feature	PROPOSED DEVICE	PREDICATE DEVICES	
		SETS GRI-FILL 3.0	SETS GRI-FILL 2.0	FLEBOSET MULTIPLE
	containers	up to 6 with MULTIPLE ancillary device.	Set)	
3.	Main Transfer Set Material	PVC with DEHP plasticizer	PVC with DEHP plasticizer	PVC with DEHP plasticizer
4.	Physical, Mechanical and Biological Specifications	Sterile / Non pyrogenic	Sterile / Non pyrogenic	Sterile / Non pyrogenic
5.	Closed system (fluid not in contact with any resusable part of the compounding device).	YES	YES	YES
6.	Integrated waste container	YES	NO	NO

From the above table, it can be established that the new device and the predicate devices are very similar. In fact, the proposed device is a newer version of the SETS GRI-FILL 2.0. As a new feature, the proposed SETS GRI-FILL 3.0 incorporate a waste bag as a permanently attached component. The 3.0 version has been designed specifically to be used in conjunction with the GRI-FILL 3.0 pharmacy compounder which also allows the addition of a determined amount of solution to a pre-filled container as well as the reconstitution of powder drugs previous to their being used in subsequent pharmacy compounding.

SUMMARY DISCUSSION OF NON-CLINICAL DATA:

All materials used in the construction of SETS GRI-FILL 3.0 have been subject to chemical and biological testing in accordance with the applicable requirements taking account of its intended use as a parenteral drug solution fluid pathway.

Functional laboratory testing performed in foreseeable operating conditions showed correct operation of the device as per its intended use, specifically including:

- accurate delivery of specified source solutions under normal conditions and stress conditions
- fluid / air leakage checking

CONCLUSIONS:

We believe the intended use, the indications for use, the functionality and the operation of both SETS GRI-FILL 3.0 and the predicate devices for fluid transfer in pharmacy compounding are essentially the same. Hence, substantial equivalence of SETS GRI-FILL 3.0 with the legally marketed device may be established.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 5 2005

Laboratorios Grifols, S.A.
C/O Mr. Morten S. Christensen
Responsible Third Party Official
Underwriters Laboratories, Incorporated
1655 Scott Boulevard
Santa Clara, California 95050-4169

Re: K050339
Trade/Device Name: Sets Gri-Fill 3.0
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: LHI
Dated: February 10, 2005
Received: February 11, 2005

Dear Mr. Christensen:

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 such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K050339

GRIFOLS	TECHNICAL EVALUATION DOCUMENTATION	# Document: TED-SETS GRI-FILL 3.0-09
SECTION 09 – SETS GRI-FILL 3.0: INDICATIONS FOR USE STATEMENT		

Indications for Use

510(k) Number (if known): K050339

Device Name: SETS GRI-FILL 3.0

Indications for Use:

SETS GRI-FILL 3.0 1 WAY and 2 WAY fluid transfer sets are ancillary devices used in conjunction with the GRI-FILL 3.0 pharmacy compounder in the hospital pharmacy to provide a fluid pathway through which one or two source substances are delivered into a final IV container or syringe.

SETS GRI-FILL 3.0 MULTIPLE fluid transfer sets are ancillary devices used as fluid pathways 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 source containers may be delivered into a final IV container.

This device should not be used with lipids.
This device is intended to be used by trained health-care personnel. It is restricted to sale by or on the order of a physician.

Prescription Use __X__ (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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number K050339