K033682

DEC 17 2003

GRIFOLS	TECHNICAL EVALUATION DOCUMENTATION	# Document: TED-SETS GRI-FILL 2.0-01

SECTION 1 – SETS GRI-FILL 2.0: 510(k) SUMMARY

DATE OF SUBMISSION: 2003-07-30

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DEVICE TRADE NAME: SETS GRI-FILL 2.0
COMMON NAME: I.V. FLUID TRANSFER SETS
CLASSIFICATION NAME: I.V. FLUID TRANSFER SETS (21 CFR 880.5440)

PREDICATE DEVICE: Exacta-Mix 2400 Compounding System Administration Set (BAXA)
Automix 3+3 Compounder Transfer Set (BAXTER HEALTHCARE)

DEVICE DESCRIPTION:

SETS GRI-FILL 2.0 are fluid transfer sets for use with the GRI-FILL 2.0 pharmacy compounding device in order to compound or mix different multi-ingredient solutions and to channel them into a final suitable container. The set is a disposable component of the compounding device made up of a syringe, a distributor and tubing to channel the fluid. Sets are available for 1 or 2 source solutions. Also a Luer female – female adapter is available as an accessory to the 1 or 2 way transfer sets. The model Luer Connection Tube can be joined to the 1 way or 2 ways sets as prolongation for connection to source solution containers with luer terminals.

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INTENDED USE:

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.

SUMMARY OF COMPARISON WITH PREDICATE DEVICE:

In the establishment of substantial equivalence, SETS GRI-FILL 2.0 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	SETS GRI-FILL	PREDICATES	
			BAXA Exacta-Mix Set	BAXTER Automix 3+3 (set presented together with compounder)
1.	Intended use / Claims	SETS GRI-FILL 2.0 are disposable components of the GRI-FILL 2.0 pharmacy compounding system used to provice 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.	Exacta-Mix 2400 Compounding System Administration set is a disposable component of a compounding device used in the pharmacy to compound multiple source ingredients into one final solution. This device is not intended for direct patient hook-up.	Positive displacement fluid compounding system employing the 3+3 compounder, TRANSFER SETS, empty Viaflex or Travamulsion containers and multitask computer software to provide compounding of a wide variety of fluids
2.	Technological features: - Sterilization - Direct patient hook-up - Source solutions	Ethylene Oxide NO 2	Ethylene Oxide NO Multiple	Radiation NO 6
3.	Main Transfer Set Materials	PVC with DEHP plasticizer	PVC	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

From the above table, it can be established that the new device and the predicate devices are very similar.

SUMMARY DISCUSSION OF NON-CLINICAL DATA:

All materials used in the construction of SETS GRI-FILL 2.0 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 transfer set.

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 2.0 and the predicate devices for fluid transfer in pharmacy compounding are essentially the same. Hence, substantial equivalence of SETS GRI-FILL 2.0 with the legally marketed devices may be established.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 17 2003

Laboratories Grifols, S.A.
Ms. Susan Gill
Responsible Third Party Official
Underwriters Laboratories, Incorporated
12 Laboratory Drive
Research Triangle Park, North Carolina 27709-3995

Re: K033682
Trade/Device Name: Set GRI-FILL 2.0-1 way ; 2.0-2 ways ; Luer Connection Tube
Regulation Number: 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: LHI, NEP
Dated: December 11, 2003
Received: December 12, 2003

Dear Ms. Gill:

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.

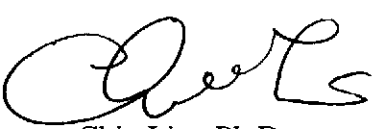
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 594-14618. 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/dsma/dsmamain.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

PREMARKET NOTIFICATION
INDICATIONS FOR USE STATEMENT
(as required by ODE for all 510(k) received after Jan. 1, 1996)

510(k) Number: _____

Device Name: SETS GRI-FILL 2.0

Indications for Use:

All models of SETS GRI-FILL 2.0 fluid transfer sets are ancillary devices used in conjunction with the GRI-FILL 2.0 pharmacy compounding device in hospital pharmacy to provide a fluid pathway through which one or more source solutions are delivered into a single Gri-bag or Gri-flex container or into a standard syringe or pump.
The device should not be used with lipids.
It is restricted to sale by or on order of a physician.

(Do not write below this line. Continue on another page in needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Patricia Cucinotta

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

510(k) Number: K033682

Prescription Use ✓ (Per 21 CFR 801.109) OR Over-The-Counter Use ___