K031419

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GRIFOLS	TECHNICAL EVALUATION DOCUMENTATION	# Document: TED-GRIFLEX-01
SECTION 1 - GRI-FLEX: 510(k) SUMMARY		

DATE OF SUBMISSION: 2003-02-03

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Technical Director

DEVICE TRADE NAME: GRI-FLEX
COMMON NAME: I.V. BAG *with in-line 0.2µm filter*
CLASSIFICATION NAME: I.V. CONTAINER (880.5025 *KPE and 880.5440, NEP) with in line filter (880.5440, FPB)*

PREDICATE DEVICE: (BAG) VIAFLEX PLASTIC CONTAINER (BAXTER)
(FILTER) PALL SUPOR AEF

DEVICE DESCRIPTION:

GRI-FLEX is a single-use, non-pyrogenic flexible empty container with incorporated 0,2 µm filter. It is supplied sterile in sealed peel-pack pouches and is available in volume capacities of 100 ml, 250 ml, 500 ml and 1000 ml.

INTENDED USE:

GRI-FLEX is a bag with an incorporated 0.2 µm filter for the removal of undesired particulate or microbial matter intended for use as a container in the preparation of drug solutions with the GRI-FILL system.

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SUMMARY OF COMPARISON WITH PREDICATE DEVICE:
In the establishment of substantial equivalence, the GRI-FLEX device is compared with 2 predicate devices (bag + filter) due to the fact that it is essentially a combination of these 2 devices marketed as a single unit.

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

#	Characteristic / Feature	GRI-FLEX	PREDICATE	
			BAG	FILTER
1.	Filter membrane	Polyethersulphone	N/A	Polyethersulphone
2.	Filter pore	0.2µm	N/A	0.2µm
3.	Filter housing	Polypropylene	N/A	Polypropylene
4.	Sterility	SAL 10^{-6} ETO	SAL 10^{-6} Gamma	SAL 10^{-6} ETO
5.	Single-use	YES	YES	YES
6.	Intended use	Bag, with an incorporated 0.2 µm filter for the removal of undesired particulate or microbial matter, intended for use as a container in the preparation of drug solutions with the GRI-FILL system.	Bag intended to be used in the preparation of drug admixtures available in sizes from 50 ml – 400 ml.	Removal by in-line filtration of inadvertent contaminants (including bacteria, particulates, and entrained air) from infused intravenous fluids.

The principal differences between the GRI-FLEX device and the predicate devices lie with the fact that the material used for the bag is different and also, the predicate devices are marketed separately whereas the GRI-FLEX is presented as an integral unit combining the two.

SUMMARY DISCUSSION OF NON-CLINICAL DATA:
According to the biocompatibility test data available for all materials and the biological testing performed on the final product, we have established that the GRI-FLEX device fulfills the requirements set out in ISO 10993 and ISO DIS 15747.

Functional testing performed *in accordance with applicable clauses of ISO DIS 15747 and USP <661> (for the bag component) and ISO 8536-4 and ASTM F838-83 (for the filter component)* shows correct operation of the device as per its intended use.

CONCLUSIONS:

We believe the intended use, the indications for use and the design for both GRI-FLEX and the combination of predicate devices are essentially the same. Moreover, the construction materials, although different, are of comparable safety and, hence, substantial equivalence of GRI-FLEX 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

NOV 2 4 2003

Laboratoris Grifols, S.A.
C/O Ms. Susan A. Gill
Responsible Third Party Official
Underwriters Laboratories, Incorporated
12 Laboratory Drive, P.O. Box 13995
Research Triangle Park, North Carolina 27709-3995

Re: K031419
Trade/Device Name: GRI-FLEX
Regulation Number: 880.5025, 880.5440
Regulation Name: I.V. Container, Intravascular Administration Set
Regulatory Class: II
Product Code: KPE, NEP, FPB
Dated: November 12, 2003
Received: November 13, 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.

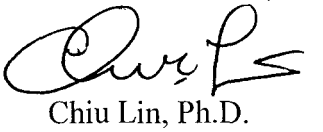
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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) 594-4618. 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: GRI-FLEX

Indications for Use:

All models of GRI-FLEX are flexible I.V. bags, with incorporated 0.2 µm filter for the removal of undesired particulate or microbial matter, for use with the GRI-FILL pharmacy compounding system as a container in the preparation of drug solutions. The drug solution is later administered to the patient by connecting the bag to an I.V. administration set. This device is intended to be used by trained health-care personnel. 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 od CDRH, Office of Device Evaluation (ODE)

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

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

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