K082511

510(k) Summary

807.92(c)

JAN 16 2009

SPONSOR **807.92(a)(1)**

Company Name	MEDIGARD LIMITED
Company Address	Suite 14A, Tedder Terraces 26-30 Tedder Avenue Main Beach, 4217 Queensland Australia
Telephone	61 7 5528 0370
Contact Person	Dr Peter W Clark

Summary Preparation Date August 25, 2008

DEVICE NAME **807.92(a)(2)**

Trade Name	Medigard Blood Collection Device
Common/Usual Name	Blood Collection Tube Holder
Classification Name	Needle, Hypodermic, Single Lumen
Regulation Number:	CFR21 880 5570
Product Code	FMI
Device Class	Class II

PREDICATE DEVICE **807.92(a)(3)**

Legally Marketed Equivalent Device

Company	*Product*	*510(k) #*
Safe T Medical Devices	Blood Collection Tube Holder Vanish Point Small Tube Adapter Collection Device	K 971763

DEVICE DESCRIPTION **807.92(a)(4)**

The Medigard Blood Collection Device Consists of two Parts 1) a blood collection tube holder and 2) an evacuated sharps collection tube Neither part comes into contact with the patient and no fluids flow through the Medigard Blood Collection Device to the patient Normal standard blood collection tubes and blood collection needles are used to collect blood samples as per normal standard procedures The device is intended to be used to provide a safe and reliable method of collection of blood samples from a patient using standard evacuated blood collection tubes The device is designed to prevent accidental needle stick injury At the end of the procedure, the needle is retracted into the Medigard evacuated sharps collection tube

K085211

DEVICE INTENDED USE 807.92(a)(5)

The function of the Medigard Blood Collection Device is to provide a safe and reliable method for facilitating blood withdrawal from a patient into evacuated blood collection tubes without exposing the healthcare worker to an accidental needle stick injury

COMPARISON OF TECHNICAL CHARACTERISTICS 807.92(a)(6)

	Features	Medigard Limited	Retractable Technology Inc. K971763
	Proprietary Name	Medigard Blood Collection Device	Vanish Point® Blood Collection Tube Holder
	Intended Use	Medical device to enable to withdrawal of blood samples from a patient The device is designed to prevent accidental needle stick injuries during and after the procedure The needle is retracted via a vacuum, and can not be accessed after retraction	Medical device to enable withdrawal of blood samples from a patient The device is designed to prevent accidental needle stick injuries The needle is retracted via a spring mechanism
	Material Composition	Plastic	Plastic and metal
	Device Components	Two Components 1 Collection tube for blood collection 2 Vac tube for safety feature	One Component 1 Collection tube with spring mechanism
	Product Design - Safety Feature Mode of Operation	Safety feature activated by user Needle retracted via vacuum and can not be accessed after retraction	Safety feature activated by user Needle retracted by a spring mechanism
	Product Design – Safety Feature Activation Mechanism	A separate (Medigard) evacuated collection tube is inserted into the Tube Holder to initiate activation This couples with & releases the hub (containing needle) allowing it to be retracted into the tube via vacuum The tube is automatically locked into the holder preventing further access to the needle	A cap at the opening of the Tube Holder is pressed closed to dislocate the hub (containing needle) This allows the spring to drive the hub into the rear of the holder thereby sheathing the needle
	Disposable volume i.e. Space occupied in a sharps container	Approx 28cc	Approx 35cc
	Sterilization	Non-sterile	Non-sterile
	Biocompatibility	Device does not contact patient	Device does not contact patient

Substantial Equivalence Discussion of Similarities and Differences:
The Medigard Blood Collection Device is similar to the Vanish Point Blood Collection Tube Holder in

- Intended Use prevention of needle sticks by the safe retraction of the needle
- Materials plastic (Medigard), plastic/metal (Vanish Point)
- Design Retraction of Needle

- Where used Healthcare facilities
- Target Population Healthcare professionals
- Performance Testing –Bench Testing and Simulated Use Testing

Differences

- Method of Retraction Vacuum (Medigard) Spring mechanism (Vanish Point)

The Medigard Blood Collection Device introduces no new questions concerning the safety or effectiveness and is thus substantially equivalent to the predicate device

SAFETY and EFFECTIVENESS 807.92(b)

Bench Testing and Simulated Use testing were performed

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 16 2009

Medigard Limited
C/O Mr E J Smith
Smith Associates
1468 Harwell Avenue
Crofton, Maryland 21114

Re K082511
Trade/Device Name Medigard Blood Collection Device
Regulation Number 21 CFR 880 5570
Regulation Name Hypodermic Single Lumen Needle
Regulatory Class II
Product Code FMI
Dated December 7, 2008
Received December 11, 2008

Dear Mr Smith

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807 97) For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474 For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464 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 E. Watson for
Ginette Y Michaud, M D
Acting Division 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): K082511

Device Name: Medigard Blood Collection Device

Indications For Use:

Medical device to enable withdrawal of blood samples from a patient. The device is designed to prevent accidental needle stick injuries. The needle is retracted via a retraction tube.

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) Page 1 of ___1__

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

510(k) Number: K082511