510(k) Summary
807.92(c)

JAN 16 2009

SPONSOR
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
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
Legally Marketed Equivalent Device
Company: Safe T Medical Devices
Product: Blood Collection Tube Holder
Vanish Point Small Tube Adapter
Collection Device

DEVICE DESCRIPTION
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.
DEVICE INTENDED USE

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

<table>
<thead>
<tr>
<th>Features</th>
<th>Medigard Limited</th>
<th>Retractable Technology Inc.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proprietary Name</td>
<td>Medigard Blood Collection Device</td>
<td>Vanish Point® Blood Collection Tube Holder</td>
</tr>
<tr>
<td>Intended Use</td>
<td>Medical device to enable 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.</td>
<td>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.</td>
</tr>
<tr>
<td>Material Composition</td>
<td>Plastic</td>
<td>Plastic and metal</td>
</tr>
<tr>
<td>Device Components</td>
<td>Two Components</td>
<td>One Component</td>
</tr>
<tr>
<td></td>
<td>1 Collection tube for blood collection</td>
<td>1 Collection tube with spring mechanism</td>
</tr>
<tr>
<td></td>
<td>2 Vac tube for safety feature</td>
<td></td>
</tr>
<tr>
<td>Product Design - Safety</td>
<td>Safety feature activated by user</td>
<td>Safety feature activated by user</td>
</tr>
<tr>
<td>Feature Mode of Operation</td>
<td>Needle retracted via vacuum and can not be accessed after retraction</td>
<td>Needle retracted by a spring mechanism</td>
</tr>
<tr>
<td>Product Design - Safety</td>
<td>A separate (Medigard) evacuated collection tube is inserted into the Tube Holder to initiate activation. This couples with &amp; 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.</td>
<td>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.</td>
</tr>
<tr>
<td>Activation Mechanism</td>
<td>Approx 28cc</td>
<td>Approx 35cc</td>
</tr>
<tr>
<td>Disposable volume i.e.</td>
<td>Non-sterile</td>
<td>Non-sterile</td>
</tr>
<tr>
<td>Space occupied in a sharps</td>
<td>Device does not contact patient</td>
<td>Device does not contact patient</td>
</tr>
<tr>
<td>container</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sterilization</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Biocompatibility</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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.
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” (21 CFR 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,

[Signature]
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