510(k) Summary – Revised September 27, 2010

Owner's Information:	MediPurpose Pte. Ltd. 3850 Holcomb Bridge Road, Suite 350 Norcross, GA 30092
Contact Person:	Julie Stephens, President/Consultant Regulatory Resources Group, Inc.
510(k) Number:	K101145
Date Prepared:	September 2010
Trade/Proprietary Name:	SurgiLance® Safety Lancets
Common Name:	Blood Lancets
Class:	I - Lancet with Sharps Prevention Feature
Legally Marketed Predicate Devices:	BD Microtainer® Contact-Activated Lancet, K822209

OCT 2 1 2010

Device Description:

The MediPurpose SurgiLance® Safety Lancets is a needle or blade device used to prick a patient's finger to draw a micro-sample of blood which can then be tested for an array of diagnostic assays. Point-of-Care (POC) tests currently using micro-sample quantities of whole blood include glucose, cholesterol, HIV, Hepatitis, A1C, Allergies, Lactate, HgB, H.Pylori, Creatinine, Mono, PT, D-Dimer, Anemia, Thyroid, Triglycerides, Ketones, Prostate, IgE, Chagas and more. Lancets are commonly used in hospitals, clinics, physician offices, laboratories, OB/GYN practices, oncology departments, emergency medical services, nursing homes and blood banks. The outside plastic casing is designed to be ergonomic for the user and compatible with the test site, usually a human finger. The device is available with either a needle or blade, each with different depths of penetration, to provide optimal blood flow for different applications and skin types.

The SurgiLance® Safety Lancet is safely retracted and concealed before and after use. The user simply removes the protective cap, places the red raised platform end onto the patient's test site, and gently push the lancet down against the test site to activate the lancet mechanism. Once the lancet is used, it is rendered inoperative, providing added safety for patient and clinician. The device is discarded in a sharps container after use.

The SurgiLance® Safety Lancet comes in six models: two low flow, one medium flow, one medium-high flow, and two high flows. The six models are differentiated by their casing color.

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Intended Use:

The SurgiLance® Safety Lancet is a puncture device to obtain micro blood samples. The SurgiLance® Safety Lancet has a sharps prevention feature to protect the user from a needlestick injury.

Similarities and Differences of the Proposed Devices to the Predicate Devices:

Similarities

The SurgiLance® Safety Lancet has the same basic technology characteristics for a lancet with sharps injury prevention. It is intended for piercing the skin, as the predicate devices, and the indications for use are the same. The materials are comparable in that the needles and blades all use medical grade stainless steel and the housings are made of plastics.

Differences

The SurgiLance® Safety Lancet utilizes some of the same materials, specifically the use of medical grade stainless steel for the lancet needles and blades but may use different types or grades of plastics for the housings, caps, and triggers. All the materials are known biocompatible materials that have been used in lancets or other similar medical devices.

Conclusion:

The SurgiLance® Safety Lancet has the same principles of operation, intended use, and technological characteristics as the predicate devices. The sharps prevention feature was fully tested to the FDA's guidance document as demonstrated in the performance testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

MediPurpose Pte, Ltd.
% Regulatory Resources Group, Inc.
Ms. Julie Stephens
111 Laurel Ridge Drive
Alpharetta, Georgia 30004

OCT 21 2010

Re: K101145
Trade/Device Name: SurgiLance® Safety Lancet
Regulation Number: 21 CFR 878.4800
Regulation Name: Manual surgical instrument for general use
Regulatory Class: I
Product Code: FMK
Dated: September 16, 2010
Received: September 17, 2010

Dear Ms. Stephens:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

Revised - September 2010

510(k) Number (if known): K101145

Device Name: SurgiLance® Safety Lancet

Indications for Use:

The SurgiLance® Safety Lancet is a puncture device to obtain micro blood samples. The SurgiLance® Safety Lancet has a sharps prevention feature to protect the user from a needlestick injury.

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Prescription Use ___X___ AND/OR Over-The-Counter Use ___X___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. Ogden for mxm
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K101145