MediPurpose Pte. Ltd.
Abbreviated 510(k) # K101417- babyLance™ Heel Incision Device

510(k) Summary

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:	K101417
Date Prepared:	September 2010 - Revised
Trade/Proprietary Name:	babyLance™ Heel Incision Device
Common Name:	Infant Heel Lancet
Classification Name:	Lancet, Blood (21 CFR 878.4400)
Class:	I - Lancet with Sharps Prevention Feature
Product Code:	FMK
Legally Marketed Predicate Devices:	BD Microtainer® Quikheel™ Lancet, 510(k) # K822209

OCT 19 2010

Device Description:

The MediPurpose babyLance™ Heel Incision Device is designed to be a one handed automated incision device for use in heel sticks of newborn and neonatal infants (also called preemie infants). A heel stick is a procedure in which a newborn baby's heel is pricked for blood collection for use in newborn screening tests. The outside plastic casing is designed to be ergonomic for the user and compatible with an infant's foot. There are three integrated components to the sharps prevention feature: a) a locking mechanism to prevent accidental activation of the device because the user breaks off the trigger locking mechanism from the device, b) once the locking mechanism has been removed, the device is positioned on the newborn's heel and the user depresses the trigger to activate the blade to make an incision, c) once the blade has been triggered, the device is immediately removed from the infant's foot which retracts the blade. The device is discarded in a sharps container after use.

The babyLance™ comes in two models, preemie and newborn. The preemie model is to be used on pre term neonates, while the newborn model is for full term neonates. The two models are differentiated by color.

Intended Use:

The babyLance™ is an incision device to obtain a blood sample from a heel stick in newborn and preemie infants. The babyLance™ has a sharps prevention feature to protect the user from a sharps injury.

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

Similarities
The babyLance™ Heel Incision Device has the same basic technology characteristics for an infant heel stick lancet with sharps injury prevention. It is intended for piercing the heel skin of a preemie or newborn, as the predicate devices, and the indications for use are the same. The materials are comparable in that the blades all use medical grade stainless steel and the housings are made of plastics.

Differences
The babyLance™ Heel Incision Device utilizes some of the same materials, specifically the use of medical grade stainless steel for the lancet blades but may use different types or grades of plastics for the housings and triggers. All the materials are known biocompatible materials that have been used in lancets or other similar medical devices.

Conclusion:

The babyLance™ Heel Incision Device has the same principles of operation, intended use, and technological characteristics as the predicate devices. Testing was completed for the sharps prevention feature to the FDA's guidance document, which included product drop tests, cut profiles with comparisons to the predicate device, and simulated use. The performance testing reports are contained in the 510(k) documentation (Section C).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MediPurpose Ptd., Ltd.
% Regulatory Resources Group, Inc.
Ms. Julie Stephens
President-Consultant
111 Laurel Ridge Drive
Alpharetta, Georgia 30004

OCT 19 2010

Re: K101417
Trade/Device Name: babyLance™ Heel Incision Device
Regulation Number: 21 CFR 878.4800
Regulation Name: Manual surgical instrument for general use
Regulatory Class: Class I
Product Code: FMK
Dated: September 27, 2010
Received: September 29, 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,

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

Enclosure

K101417

Indications for Use

510(k) Number (if known): K101417

OCT 19 2010

Device Name: babyLance™ Heel Incision Device

Indications for Use:

The babyLance™ is an incision device to obtain a blood sample from the heel of newborn and preemie infants. The babyLance™ has a sharps prevention feature to protect the user from a sharps injury.

Prescription Use _____ 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)

Mark A. Nichols for mxm

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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