

MediPurpose™

Lancing Devices

White Paper: Reinventing a Better **babyLance™** Safety Heelstick



Obtaining a U.S. FDA 510(k) for Sharps
Prevention Features



In February 2013, MediPurpose™—a manufacturer and master distributor of medical products—received U.S. FDA 510(k) clearance to market its redesigned babyLance™ safety heelstick with a sharps prevention indication.¹

This white paper illustrates:

- The meaning and significance of a 510(k) for medical devices with sharps injury prevention features.
- Why MediPurpose re-applied for babyLance's 510(k)—despite receiving clearance in October 2010 for its previous heelstick device.
- How MediPurpose identified and met the requirements for the 510(k) application.
- The procedures for submitting a 510(k) application.



¹ "MediPurpose Receives U.S. FDA 510(k) Clearance for Redesigned babyLance Safety Heelstick." 20 February 2013. www.medipurpose.com

After launching the highly successful and innovative SurgiLance™ safety lancet in 1999, medical product manufacturer and master distributor MediPurpose™ introduced a complementary product in 2010, the babyLance™ safety heelstick.

However, within a few months of launch, MediPurpose realized that the babyLance's innovative design was not fully meeting the preferences and expectations of users in the U.S. market.

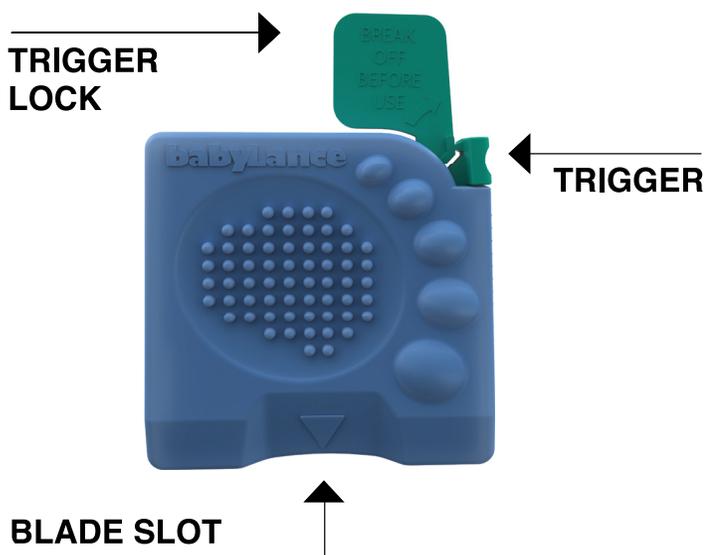
Although a number of U.S. healthcare facilities expressed a desire to continue use of the product, feedback indicated that the device needed some modifications in order to fully satisfy customer demands. This included reports that some users preferred a “pull” trigger rather than the babyLance's “push forward” trigger.

MediPurpose elected not to withdraw the product from the market, but rather, it reduced its production and marketing programs for babyLance. The company then initiated a year-plus period of intensive research, redesign and testing, which resulted in its fully redesigned babyLance safety heelstick that was launched worldwide in 2012.

U.S. FDA 510(k) for Medical Devices with Sharps Injury Prevention Features

Each manufacturer that wants to market in the United States a Class I, II or III medical device intended for human use—for which a Premarket Approval (PMA) is not required—must submit a Premarket Notification (510k) to the U.S. Food and Drug Administration (FDA), unless the device is exempt from 510(k) requirements of the Federal Food, Drug, and Cosmetic Act.¹

A 510(k) is a premarket submission made to the FDA to demonstrate that the device to be marketed is at least as safe and effective, (that is, substantially equivalent) to a legally marketed device.²



Before marketing a device, each submitter must receive an order (in the form of a letter) from the FDA that finds the device to be substantially equivalent (SE) and states that the device can be marketed in the U.S. This order “clears” the device for commercial distribution.

If the device falls into a generic category of exempted class I devices,³ a Premarket Notification (510k) application and FDA clearance is not required before marketing the device in the United States.

¹ Learn more about Premarket Approvals and Notifications at www.fda.gov/medicaldevices/deviceregulationandguidance/howtomarketyourdevice/premarketsubmissions/premarketnotification510k/default.htm.

² Per U.S. FDA regulation 21 CFR 807.92(a)(3). Learn more at www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142651.htm.

³ Learn more about 510(k) exemptions and Good Manufacturing Practice (GMP) requirements at www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpdcd/315.cfm.

Heelsticks or heel incision devices are generally classified as blood lancet devices under class I⁴ and are therefore 510(K) exempt.

However, if the device exceeds the limitations of exemptions of the device classification (e.g., the device has a new intended use), then a 510(k) must be submitted. Heelsticks with sharps injury prevention features are considered as extending the use of the device, and therefore a 510(k) is required.

A sharps injury prevention feature is designed to protect the user from a sharps injury. Some sharps injury prevention features are incorporated as integrated components of finished devices. Others are marketed separately as accessories that are attached to a device by the user at the point of use, for example, a needle shield.

A heelstick that does not have 510(k) clearance, even if it appears to be designed to protect the user from a sharps injury, cannot be labeled as a safety heelstick.

MediPurpose received FDA 510(k) clearance in October 2010 for its first babyLance heelstick device.⁵

⁴ Learn more about medical device classifications at www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpd/classification.cfm?ID=4952.

⁵ "MediPurpose Receives U.S. FDA 510(k) Clearance for babyLance Infant Heel Incision Device with Sharps Prevention." 11 November 2010. www.medipurpose.com

U.S. FDA 510(k) Requirements for a Modified Device

When MediPurpose started to redesign the babyLance in 2011, the company had to evaluate whether a new 510(k) application was required for the modified babyLance.¹

A new complete 510(k) application is required for changes or modifications to an existing device, where the modifications could significantly affect the safety or effectiveness of the device, or the device is to be marketed for a new or different indication.²

When a 510(k) holder decides to modify an existing device, the holder must decide whether the proposed device modification(s) requires submission of a 510(k). It is not FDA's intent that a 510(k) must be submitted for every modification.

Examples of modifications that may require a 510(k) submission include, but are not limited to, the following:

- Design
- Structural material
- Sterilization method
- Manufacturing method
- Stability or expiration claims
- Patient or user safety features
- Sterile barrier packaging material
- Operating parameters or conditions for use

Every modification to the device should be reviewed by appropriate personnel to determine if it affects safety or efficacy. Any design or labeling change to a device should be evaluated and documented.³

¹ Learn more about 510(k) requirements for modified devices at www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134575.htm.

² Per U.S. FDA regulation 21 CFR 807.92(a)(3). Learn more at www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142651.htm.

³ Per 21 CFR 820, Quality System regulation. Learn more at www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?cfrpart=820.

If it is determined that the modification is not significant, the basis for this decision should be documented with supporting data in the 510(k) holder's device master file. If it is determined that the modification is significant, a new 510(k) must be submitted to FDA.



There are no provisions for a 510(k) amendment or supplement to the existing 510(k); instead, a new 510(k) must be submitted. However, the FDA developed a streamlined 510(k) process for modifications to a device cleared under 510(k), called the Special 510(k).

The FDA has published a guidance document to provide direction to manufacturers on deciding when to submit a 510(k) for a change to an existing device.⁴ Using the FDA's guidance document, MediPurpose evaluated the changes to the babyLance as follows:

- **Labeling Changes**
 - Labeling changes to the Instructions For Use (IFU) do not affect the indications for use.
- **Technology, Engineering or Performance Specifications Changes**

The redesigned babyLance involves the following significant changes:

 - Change in ergonomics of the patient/user interface
 - Addition of spring to provide consistent incision profile
- **Materials Changes**
 - Internal hub changed to a different plastic material.

MediPurpose decided that a new 510(k) should be submitted for the redesigned babyLance primarily due to the engineering and performance specifications changes. Pending FDA clearance for the new safety babyLance, MediPurpose commenced marketing of the redesigned babyLance as a Class I device without any safety claims.

With FDA clearance of the redesigned babyLance's 510(k) in February 2013, MediPurpose can now call it a safety heelstick.

⁴ Learn more about 510(k) applications for changes to existing devices at www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080235.htm.

U.S. FDA 510(k) Requirement for Medical Devices with Sharps Injury Prevention Features

The FDA has developed a guidance document to assist the industry in preparing premarket notification (510k) submissions for medical devices that incorporate a sharps injury prevention feature (e.g., anti-needlestick feature).¹ An Abbreviated 510(k) submission is recommended.

The FDA guidance document recommends the following:

Design Recommendations for Sharps Injury Prevention Features

The following design criteria are recommended specific to heelstick devices:

- The user should be able to easily tell whether the sharps injury prevention feature is activated.
- Once activated, the sharps injury prevention feature cannot be deactivated and should remain protective through disposal.
- The sharp should be fully retracted within the housing of the device.
- The use of color should achieve a specific purpose, (e.g., differentiate device models or sizes) and conform to user conventions.

Risks to Health

The FDA has identified the following risks to health generally associated with the use of sharps injury prevention features:

Identified Risk	Recommended Mitigation Measures
Device Malfunction	Bench Testing
Adverse Tissue Reaction	Biocompatibility
Infection	Simulated Clinical Studies
	Sterilization
Improper Use	Labeling

¹ Learn more at www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm071663.htm.

babyLance Testing

MediPurpose conducted the following tests to confirm the proper function and safety of the babyLance safety heelstick:

- Drop Test
- Activation Force
- Activation Distance
- Incision Profile
- Sterilization
- Biocompatibility

Simulated Clinical Use Testing

The FDA recommends that for many devices with sharps safety features, it is feasible to test 500 devices, which will enable detection of grossly defective devices at a one-percent level. If there were no failures observed in a test run of 500 devices, we would be 97.5 percent confident that the true failure rate was no higher than 0.7 percent, and 99.5 percent confident that it was no higher than 1.1 percent.

MediPurpose conducted a simulated clinical use test in early 2012:

- Test Facilities: 5
- Test Users: 33
- Test Units: 501

The results are as follows:

- The trigger- lock prevents accidental activation: 100%
- The blade was shielded prior to activation: 100%
- The blade was shielded after activation: 100%
- The device cannot be reused after activation: 100%



U.S. FDA 510(k) Application Process

An applicant may choose from three types of Premarket Notification 510(k) submissions for marketing clearance:¹

Traditional 510(k)

The Traditional 510(k) method may be used under any circumstances (e.g., any original 510(k) or for a modification to a previously cleared device under 510(k)). It is the original complete submission as provided in 21 CFR 807.

Special 510(k)

The Special 510(k) is used for a modification to a device that has been cleared under the 510(k) process.

Abbreviated 510(k)

Device manufacturers may choose to submit an Abbreviated 510(k) when:

- A guidance documents exists,
- A special control has been established, or
- The FDA has recognized a relevant consensus standard.

MediPurpose submitted a Traditional 510(k) application for the original babyLance and a Special 510(k) application for the redesigned babyLance. Although it is possible for the applicant to prepare and submit the 510(k) application using its internal resources, MediPurpose elected to use a consultant with experience in the 510(k) process.

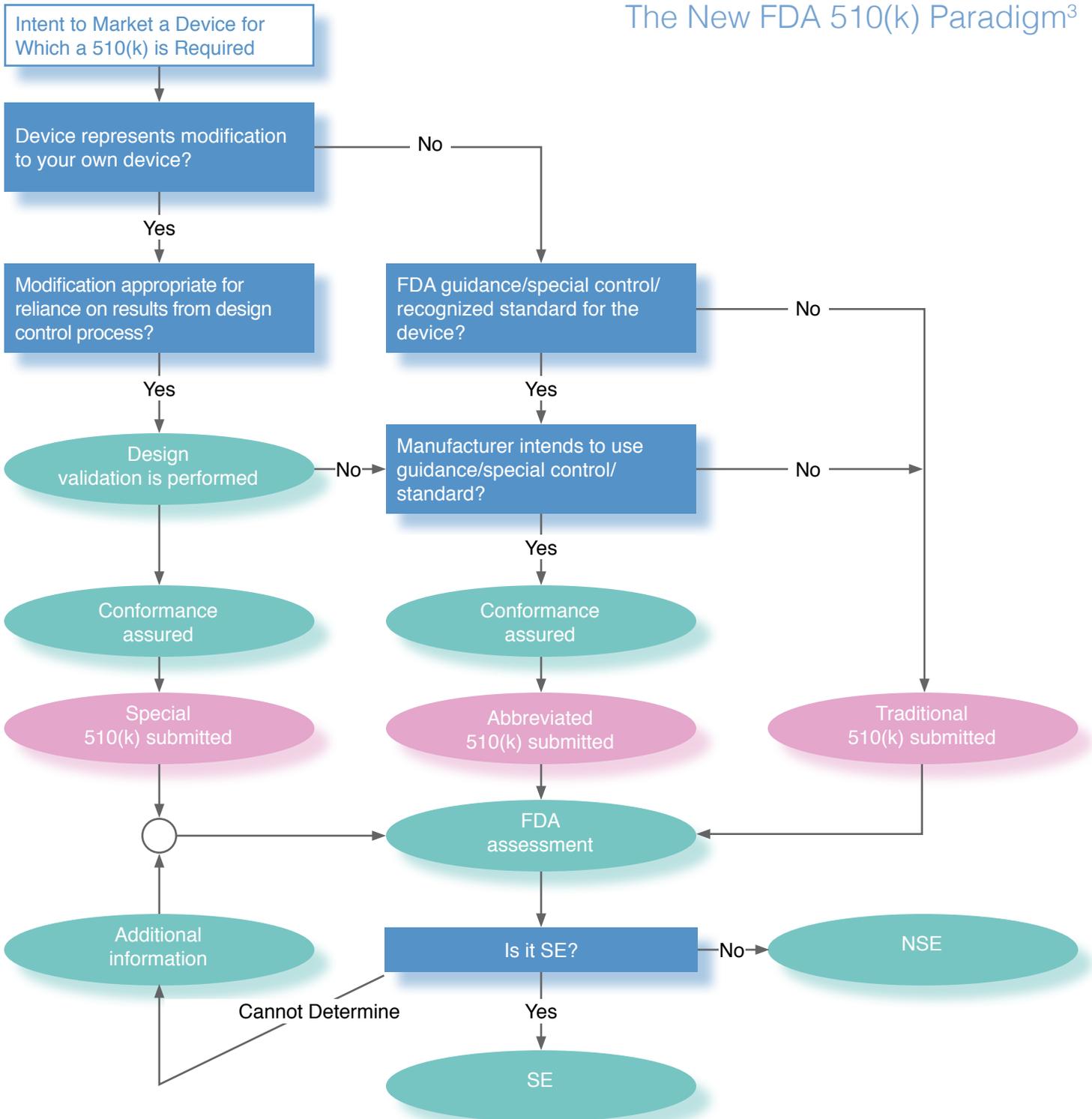
The 510(k) for the original babyLance was cleared within five months, while the special 510(k) for the redesigned babyLance only took one month.

The FDA charges a fee for the review of Premarket Notification (510(k)) applications.² These fees are adjusted each year to account for inflation, changes in workloads and other factors. The fee paid by small businesses such MediPurpose (\$100 million or less in gross receipts or sales) is 50 percent of the standard fee.

¹ Learn more at 510(k) submission methods at www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134034.htm.

² Learn more about 510(k) application fees at www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134566.htm.

The New FDA 510(k) Paradigm³



³ "510 (k) Submission Methods." www.fda.gov/medicaldevices/deviceregulationandguidance/howtomarketyourdevice/premarket submissions/premarketnotification510k/ucm134034.htm

Based on what it learned about FDA guidelines and its knowledge about modifications to the redesigned babyLance, MediPurpose ultimately decided to submit a new “Special 510(k)” application—primarily due to the new device’s engineering and performance specification changes.



MediPurpose launched its new babyLance in August 2012 as the “babyLance heelstick”—a Class I device without any safety claims—as it awaited clearance of its 510(k) for sharps prevention feature indications which was granted in February 2013, permitting the company to market its product as the babyLance safety heelstick.

To date, babyLance is believed to be the only infant heelstick marketed in the United States with 510(k) clearance for sharps prevention features. That includes both the original and redesigned babyLance safety heelstick models.

Business Benefits of Partnering with MediPurpose™

In August 2012, MediPurpose™ launched a redesigned babyLance™ heelstick that will satisfy the unique needs of both its end-user customers and distribution partners.

The company's confidence is supported by the knowledge that the new babyLance:

- Is designed with intensive input from a diverse range of highly qualified users.
- Is capable of consistently delivering the ideal heelstick incision that yields an adequate volume of blood for collection while minimizing pain, bruising and trauma to an infant's delicate tissues and nerve endings.
- Provides preferred ergonomic features—such as a “pull trigger” activation mechanism—that is comfortable and easy to use.
- Is assured to provide safety and quality from a proven and trusted manufacturer with worldwide distribution channels.

Additionally, this interactive process further validates MediPurpose's medical product innovation methodology and capabilities.

Calls to Action

- Learn more about babyLance™
Please visit www.medipurpose.com/babylance
- Download babyLance™ product and reference guides
Please visit www.medipurpose.com/downloads
- Download other babyLance™ white papers and case studies
Please visit www.medipurpose.com/downloads
- Request no-cost samples and pricing
Please visit medipurpose.wufoo.com/forms/q7x3s5/
- Participate in clinical evaluations
Please e-mail sales@medipurpose.com
- Arrange for in-servicing from an approved distributor
Please e-mail sales@medipurpose.com



Advanced Heel Incisions

Our babyLance™ safety heelstick device was developed with more than 10 years of proven product development expertise, and leveraging the advanced thinking behind our SurgiLance™ safety lancet. The result is a precise, safe and consistent device specifically designed for babies.



Performance You Will Appreciate

The proprietary spring design provides a swift pendulum action of the cutting blade that makes a gentle incision and complies with CLSI LA4-A5 guidelines¹.

Easy on You and Baby

The industry's easiest trigger reduces finger pressure and activation distance for improved stability and incision quality, which greatly minimizes the risk of bruising.

Fits Your Hand Like a Glove

Designed with you in mind. Ergonomically, the dimples give you a secure grip. While functionally, the device cradles the baby's foot for stability and reduced rock, with visual markings that enable better alignment and a more accurate incision.

The Perfect Incision Every Time

The innovative spring design controls the consistency of the depth and width of the incision for better blood flow, without touching the baby's tender nerve fibers.

4 Easy Steps



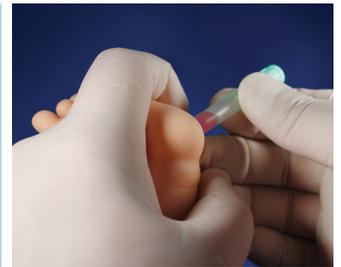
1. Select an incision site on the flat bottom surface of the heel, then clean the area.



2. Remove the Trigger Lock, but do not pull back the trigger until ready for use.



3. Align the Blade Slot with the incision site using the visual marking and pull the trigger back with your index finger. Discard.



4. Gently wipe away the first droplet of blood, then collect the desired quantity. That's it.

Product	Code	Incision Depth	Color	Packaging
 Premie	BLP	0.85mm	Pink	50/box 200/case
 Newborn	BLN	1.00mm	Blue	50/box 200/case

[medipurpose.com/babylance](https://www.medipurpose.com/babylance)

1. Clinical and Laboratory Standards Institute. Blood Collection on filter paper for newborn screening programs – Fifth Edition; Approved Standard. CLSI document LA4-A5. Wayne, PA: CLSI, 2007.

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