FDA 510(k) Premarket Notification

K130132 BABYLANCE HEEL INCISION DEVICE

CLEARED

Feb 11, 2013
24 days to decision

K130132 · Product code: **FMK** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k130132/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Single Use Only Blood Lancet With An Integral Sharps Injury Prevention Feature (FMK)
Date received	Jan 18, 2013
Decision date	Feb 11, 2013
Days to decision	24 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Medipurpose Pte. , Ltd.**
Location	Alpharetta, GA, US
Contact	JULIE STEPHENS
510(k) history	5 submissions · 5 cleared · 2010-2022