FDA 510(k) Premarket Notification

CLEARED

K172712 gentleheel Micro-Preemie, gentleheel Preemie, gentleheel Newborn, gentleheel Toddler

Nov 6, 2017
59 days to decision

K172712 · Product code: **FMK** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k172712/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Single Use Only Blood Lancet With An Integral Sharps Injury Prevention Feature (FMK)
Date received	Sep 8, 2017
Decision date	Nov 6, 2017
Days to decision	59 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Gri Medical & Electronic Technology Co., Ltd.**
Location	Swanee, GA, US
Contact	Marty D. Paugh
510(k) history	3 submissions · 3 cleared · 2011-2017