

K172712 gentleheel Micro-Preemie, gentleheel Preemie, gentleheel Newborn, gentleheel ToddlerNov 6, 2017
59 days to decisionK172712 · Product code: **FMK** · General & Plastic SurgerySource: <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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k172712/>, Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 31, 2026