FDA 510(k) Premarket Notification

CLEARED

K220917 gentleheel Micro-Preemie, gentleheel Preemie, gentleheel Newborn, gentleheel Toddler

May 18, 2022
49 days to decision

K220917 · Product code: **FMK** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k220917/

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	Mar 30, 2022
Decision date	May 18, 2022
Days to decision	49 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Gri-Alleset, Inc.**
Location	Flowery Branch, GA, US
Contact	Marty D Paugh
510(k) history	4 submissions · 4 cleared · 2021-2024

REGULATORY CONSULTANT

Consulting firm	**Regulatory Resources Group, Inc.**
Contact	Julie Stephens

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov