FDA 510(k) Premarket Notification

K931827 CLEANLET, CLEANLET XL & KIDS

CLEARED

Sep 13, 1993
158 days to decision

K931827 · Product code: **FMK** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k931827/

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	Apr 8, 1993
Decision date	Sep 13, 1993
Days to decision	158 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Gainor Medical Europe, Ltd.**
Location	Mcdonough, GA, US
Contact	MARK J GAINOR
510(k) history	13 submissions · 13 cleared · 1990-1994

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k931827/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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