FDA 510(k) Premarket Notification

K931828 CARELET SAFETY LANCET

CLEARED

Oct 15, 1993
190 days to decision

K931828 · Product code: **FMK** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k931828/

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	Oct 15, 1993
Days to decision	190 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