FDA 510(k) Premarket Notification

K850150 ULSTER SCIENTIFIC, INC. AUTOLET LANCETS/GAINOR MED

CLEARED

Feb 21, 1985
38 days to decision

K850150 · Product code: **FMK** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k850150/

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	Jan 14, 1985
Decision date	Feb 21, 1985
Days to decision	38 days
Third-party review	No

APPLICANT

Company	**Gainor Medical**
Location	US
Contact	MARK GAINOR
510(k) history	11 submissions · 11 cleared · 1984-1987

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k850150/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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