FDA 510(k) Premarket Notification

K902430 GLUCOLET 2 AUTOMATIC LANCING DEVICE FOR OB. BLOOD

CLEARED

Aug 2, 1990
63 days to decision

K902430 · Product code: **FMK** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k902430/

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	May 31, 1990
Decision date	Aug 2, 1990
Days to decision	63 days
Third-party review	No

APPLICANT

Company	**Heraeus Kulzer, Inc.**
Location	Elkhart, IN, US
Contact	M SAVOL
510(k) history	145 submissions · 145 cleared · 1988-2009