FDA 510(k) Premarket Notification

K830001 SUPERJET BTD BLEEDING TIME DEVICE DISP

CLEARED

Sep 26, 1983
266 days to decision

K830001 · Product code: **FMK** · Hematology
Source: https://www.510kdatabase.net/k830001/

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 3, 1983
Decision date	Sep 26, 1983
Days to decision	266 days
Third-party review	No

APPLICANT

Company	**Medprobe Laboratories**
Location	Mchenry, IL, US
510(k) history	4 submissions · 4 cleared · 1982-1983