FDA 510(k) Premarket Notification

K001162 GOLDFINGER DEVICE

CLEARED

Aug 9, 2000
121 days to decision

K001162 · Product code: **FMK** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k001162/

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 10, 2000
Decision date	Aug 9, 2000
Days to decision	121 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Mali-Tech , Ltd.**
Location	Ginot Shomron 44853, IL
Contact	AHAVA STEIN
510(k) history	1 submissions · 1 cleared · 2000-2000