FDA 510(k) Premarket Notification

K943968 TUNNELER

CLEARED

Mar 1, 1995
198 days to decision

K943968 · Product code: **MDM** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k943968/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Manual, Surgical, General Use (MDM)
Date received	Aug 15, 1994
Decision date	Mar 1, 1995
Days to decision	198 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Denver Biomedicals, Inc.**
Location	Englewood, CO, US
Contact	LYNNE LEONARD
510(k) history	10 submissions · 10 cleared · 1981-2005