FDA 510(k) Premarket Notification

K955631 ORTHOPLUG HARD BONE DESIGN

CLEARED

Feb 27, 1996
78 days to decision

K955631 · Product code: **LZN** · Orthopedic
Source: https://www.510kdatabase.net/k955631/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cement Obturator (LZN)
Date received	Dec 11, 1995
Decision date	Feb 27, 1996
Days to decision	78 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Sunmed, Inc.**
Location	Clearwater, FL, US
Contact	RONALD M CARN
510(k) history	4 submissions · 4 cleared · 1993-2007