FDA 510(k) Premarket Notification

K972308 MEDNEXT 1000 DRILL

CLEARED

Aug 20, 1997
61 days to decision

K972308 · Product code: **GEY** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k972308/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Motor, Surgical Instrument, Ac-powered (GEY)
Date received	Jun 20, 1997
Decision date	Aug 20, 1997
Days to decision	61 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Mednext, Inc.**
Location	West Point Beach, FL, US
Contact	THOMAS J MICKEL
510(k) history	7 submissions · 7 cleared · 1993-1998