FDA 510(k) Premarket Notification

K841619 DRILL GUIDE

CLEARED

Jul 11, 1984
83 days to decision

K841619 · Product code: **FZX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k841619/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Guide, Surgical, Instrument (FZX)
Date received	Apr 19, 1984
Decision date	Jul 11, 1984
Days to decision	83 days
Third-party review	No

APPLICANT

Company	**Plastafil, Inc.**
Location	Walker, MI, US
510(k) history	13 submissions · 13 cleared · 1984-1984