FDA 510(k) Premarket Notification

K812506 THE ARTHROFILE

CLEARED

Sep 24, 1981
23 days to decision

K812506 · Product code: **HTR** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k812506/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Rasp (HTR)
Date received	Sep 1, 1981
Decision date	Sep 24, 1981
Days to decision	23 days
Third-party review	No

APPLICANT

Company	**Dyonics, Inc.**
Location	Walker, MI, US
510(k) history	19 submissions · 19 cleared · 1978-1990