FDA 510(k) Premarket Notification

CLEARED

K002764 HYDROCISION ARTHROJET SYSTEM WITH CAUTERY AND BURR

Nov 24, 2000
80 days to decision

K002764 · Product code: **HRX** · Orthopedic
Source: https://www.510kdatabase.net/k002764/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Arthroscope (HRX)
Date received	Sep 5, 2000
Decision date	Nov 24, 2000
Days to decision	80 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Hydrocision, Inc.**
Location	Hopkonton, MA, US
Contact	DEBBIE IAMPIETRO
510(k) history	12 submissions · 12 cleared · 1998-2025