FDA 510(k) Premarket Notification

K180315 DISKOM

CLEARED

Mar 26, 2018
49 days to decision

K180315 · Product code: **HRX** · Orthopedic
Source: https://www.510kdatabase.net/k180315/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Arthroscope (HRX)
Date received	Feb 5, 2018
Decision date	Mar 26, 2018
Days to decision	49 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Biopsybell S.R.L.**
Location	Verona, NJ, US
Contact	Tiziana Bellini
510(k) history	4 submissions · 4 cleared · 2014-2023