FDA 510(k) Premarket Notification

CLEARED

K181982 MIDAScope and Introducer Kit, and MIDASystem

Aug 21, 2018
27 days to decision

K181982 · Product code: **HRX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k181982/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Arthroscope (HRX)
Date received	Jul 25, 2018
Decision date	Aug 21, 2018
Days to decision	27 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	**Intravu, Inc.**
Location	Redwood City, CA, US
Contact	Plamena Entcheva-Dimitrov
510(k) history	2 submissions · 2 cleared · 2018-2024