FDA 510(k) Premarket Notification

K130778 DISCOSCOPES, CERVICAL ENDOSCOPES

CLEARED

Apr 14, 2014
389 days to decision

K130778 · Product code: **HRX** · Orthopedic
Source: https://www.510kdatabase.net/k130778/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Arthroscope (HRX)
Date received	Mar 21, 2013
Decision date	Apr 14, 2014
Days to decision	389 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Rz Medizintechnik GmbH**
Location	Amsterdam, NL
Contact	ANDRE WEINGREL
510(k) history	3 submissions · 3 cleared · 2008-2025