FDA 510(k) Premarket Notification

K082841 SPINAL FORAMINOSCOPE

CLEARED

Sep 9, 2009
348 days to decision

K082841 · Product code: **HRX** · Orthopedic
Source: https://www.510kdatabase.net/k082841/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Arthroscope (HRX)
Date received	Sep 26, 2008
Decision date	Sep 9, 2009
Days to decision	348 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Blazejewski Medi-Tech GmbH**
Location	Amsterdam, Nh, NL
Contact	ANGELIKA SCHERP
510(k) history	1 submissions · 1 cleared · 2009-2009