FDA 510(k) Premarket Notification

K162341 Stryker OrthoMap Precision Knee system

CLEARED

Oct 12, 2016
51 days to decision

K162341 · Product code: **OLO** · Orthopedic
Source: https://www.510kdatabase.net/k162341/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Aug 22, 2016
Decision date	Oct 12, 2016
Days to decision	51 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Stryker Leibinger GmbH & Co KG**
Location	Freiburg Im Breisgau, DE
Contact	N/A N/A
510(k) history	21 submissions · 21 cleared · 2009-2026