FDA 510(k) Premarket Notification

K183114 Corin BiPolar-i

CLEARED

Jun 5, 2019
208 days to decision

K183114 · Product code: **KWY** · Orthopedic
Source: https://www.510kdatabase.net/k183114/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Hemi-, Femoral, Metal/polymer, Cemented Or Uncemented (KWY)
Date received	Nov 9, 2018
Decision date	Jun 5, 2019
Days to decision	208 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Corin U.S.A. Limited**
Location	Tampa, FL, US
Contact	Homer Trieu
510(k) history	21 submissions · 21 cleared · 2016-2025