FDA 510(k) Premarket Notification

K112019 BENCOX ID STEM, BENCOX METAL HEAD, BENCOX BIPOLAR CUP

CLEARED

Oct 12, 2011
90 days to decision

K112019 · Product code: **KWY** · Orthopedic
Source: https://www.510kdatabase.net/k112019/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Hemi-, Femoral, Metal/polymer, Cemented Or Uncemented (KWY)
Date received	Jul 14, 2011
Decision date	Oct 12, 2011
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Corentec Co., Ltd.**
Location	West Cadwell, NJ, US
Contact	J.S. DANIEL
510(k) history	33 submissions · 33 cleared · 2010-2025