FDA 510(k) Premarket Notification

K151615 TiTHON Staple with OsseoTi Technology

CLEARED

Oct 2, 2015
109 days to decision

K151615 · Product code: **JDR** · Orthopedic
Source: https://www.510kdatabase.net/k151615/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Staple, Fixation, Bone (JDR)
Date received	Jun 15, 2015
Decision date	Oct 2, 2015
Days to decision	109 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Biomet Manufacturing Corp**
Location	Warsaw, IN, US
Contact	Patricia Sandborn Beres
510(k) history	93 submissions · 93 cleared · 2004-2023