

K181827 Affixus Natural Nail System Humeral NailDec 14, 2018
158 days to decisionK181827 · Product code: **HSB** · Orthopedic
Source: <https://www.510kdatabase.net/k181827/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Rod, Fixation, Intramedullary And Accessories (HSB)
Date received	Jul 9, 2018
Decision date	Dec 14, 2018
Days to decision	158 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Zimmer GmbH
Location	Warsaw, IN, US
Contact	Robert Tommasini
510(k) history	43 submissions · 43 cleared · 2004-2023

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