

K153378 Monster BITE Screw SystemDec 21, 2015
28 days to decisionK153378 · Product code: **HWC** · Orthopedic
Source: <https://www.510kdatabase.net/k153378/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Screw, Fixation, Bone (HWC)
Date received	Nov 23, 2015
Decision date	Dec 21, 2015
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Paragon 28
Location	Chesterland, OH, US
Contact	Frank S. Bono
510(k) history	7 submissions · 7 cleared · 2014-2018

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k153378/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 16, 2026