

K161778 ToeTac™ 10° Hammertoe Fixation SystemNov 22, 2016
146 days to decisionK161778 · Product code: **HWC** · Orthopedic
Source: <https://www.510kdatabase.net/k161778/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Screw, Fixation, Bone (HWC)
Date received	Jun 29, 2016
Decision date	Nov 22, 2016
Days to decision	146 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Restore Surgical, LLC Db a Instratek
Location	Houston, TX, US
Contact	JEFF SEAVEY
510(k) history	3 submissions · 3 cleared · 2015-2017

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k161778/> 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