

K180612 Triathlon PKR X3 Tibial Inserts, Mako X3 Uni Onlay Tibial InsertsJun 7, 2018
91 days to decisionK180612 · Product code: **HSX** · Orthopedic
Source: <https://www.510kdatabase.net/k180612/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Femorotibial, Non-constrained, Cemented, Metal/polymer (HSX)
Date received	Mar 8, 2018
Decision date	Jun 7, 2018
Days to decision	91 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Howmedica Osteonics Corp. A.K.A. Stryker Orthopaedics
Location	Malwah, NJ, US
Contact	Emily DiMambro
510(k) history	9 submissions · 9 cleared · 2016-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k180612/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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