

K182285 PK High Tibial Osteotomy Correction SystemJun 20, 2019
301 days to decisionK182285 · Product code: **KTW** · Orthopedic
Source: <https://www.510kdatabase.net/k182285/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Appliance, Fixation, Nail/blade/plate Combination, Single Component (KTW)
Date received	Aug 23, 2018
Decision date	Jun 20, 2019
Days to decision	301 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Paonan Biotech Co., Ltd.
Location	Taipei, TW
Contact	Vivi Tsai
510(k) history	6 submissions · 6 cleared · 2017-2023

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