

K191057 Park's Pectus SystemMar 19, 2020
332 days to decisionK191057 · Product code: **HRS** · Orthopedic
Source: <https://www.510kdatabase.net/k191057/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Apr 22, 2019
Decision date	Mar 19, 2020
Days to decision	332 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Tdm Co., Ltd.
Location	Gwangju, KR
Contact	Jung-Wook Choi
510(k) history	11 submissions · 11 cleared · 2018-2024

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