

K170534 PROLIXUS TOTAL KNEE SYSTEMNov 9, 2017
259 days to decisionK170534 · Product code: **JWH** · Orthopedic
Source: <https://www.510kdatabase.net/k170534/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer/metal/polymer (JWH)
Date received	Feb 23, 2017
Decision date	Nov 9, 2017
Days to decision	259 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Otis Biotech Co., Ltd.
Location	Siheung-Si, Gyeonggi-Do, KR
Contact	Sanjay Lingot
510(k) history	3 submissions · 3 cleared · 2009-2017

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