FDA 510(k) Premarket Notification

K102367 OPTIGEN TOTAL KNEE SYSTEM

CLEARED

Dec 8, 2010
110 days to decision

K102367 · Product code: **JWH** · Orthopedic
Source: https://www.510kdatabase.net/k102367/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer/metal/polymer (JWH)
Date received	Aug 20, 2010
Decision date	Dec 8, 2010
Days to decision	110 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**U&I Corp.**
Location	Uijungbu, Gyeonggi-Do, KR
Contact	GYEONG-JE KWON
510(k) history	12 submissions · 12 cleared · 2005-2014