

K213905 ONX Large External Fixation SystemAug 25, 2022
254 days to decisionK213905 · Product code: **KTT** · Orthopedic
Source: <https://www.510kdatabase.net/k213905/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Appliance, Fixation, Nail/blade/plate Combination, Multiple Component (KTT)
Date received	Dec 14, 2021
Decision date	Aug 25, 2022
Days to decision	254 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Orthonovis, Inc.
Location	Palm Coast, FL, US
Contact	Ken West
510(k) history	5 submissions · 5 cleared · 2022-2025

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