

K231829 Xenix Medical Sacroiliac Fixation SystemAug 15, 2023
55 days to decisionK231829 · Product code: **OUR** · Orthopedic
Source: <https://www.510kdatabase.net/k231829/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sacroiliac Joint Fixation (OUR)
Date received	Jun 21, 2023
Decision date	Aug 15, 2023
Days to decision	55 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ht Medical D.B.A. Xenix Medical
Location	Orlando, FL, US
Contact	Teresa Cherry
510(k) history	3 submissions · 3 cleared · 2023-2025

REGULATORY CONSULTANT

Consulting firm	Mcra, LLC
Contact	Justin Eggleton

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k231829/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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