

**K233154 SkyOPS™ Orthopedic Plate System**Dec 21, 2023  
85 days to decisionK233154 · Product code: **HRS** · Orthopedic  
Source: <https://www.510kdatabase.net/k233154/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Sep 27, 2023
Decision date	Dec 21, 2023
Days to decision	85 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Sky Surgical, LLC</b>
Location	Sandpoint, ID, US
Contact	Jeff Sander
510(k) history	1 submissions · 1 cleared · 2023-2023

**REGULATORY CONSULTANT**

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Consulting firm	<b>MRC Global, LLC</b>
Contact	Danielle Besal

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

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k233154/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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