

**K213978 TELIGEN System**Oct 18, 2022  
302 days to decisionK213978 · Product code: **HRX** · Orthopedic  
Source: <https://www.510kdatabase.net/k213978/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Arthroscope (HRX)
Date received	Dec 20, 2021
Decision date	Oct 18, 2022
Days to decision	302 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Medos International SARL</b>
Location	Raynham, MA, US
Contact	Daria Bochenek
510(k) history	96 submissions · 96 cleared · 2010-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k213978/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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