

K200911 MIRA AdapterJun 2, 2020
57 days to decisionK200911 · Product code: **HRN** · Ophthalmic
Source: <https://www.510kdatabase.net/k200911/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Cryophthalmic, Ac-powered (HRN)
Date received	Apr 6, 2020
Decision date	Jun 2, 2020
Days to decision	57 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Phakos
Location	Montreuil, FR
Contact	Olivier Aumaitre
510(k) history	4 submissions · 4 cleared · 2017-2020

REGULATORY CONSULTANT

Consulting firm	The OrthoMedix Group, Inc.
Contact	J.D. Webb

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/k200911/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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