

K180195 Frigitronics adapterMar 16, 2018
51 days to decisionK180195 · Product code: **HRN** · Ophthalmic
Source: <https://www.510kdatabase.net/k180195/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Cryophthalmic, Ac-powered (HRN)
Date received	Jan 24, 2018
Decision date	Mar 16, 2018
Days to decision	51 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/k180195/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 20, 2026