

K173944 Endocular Viewing Lenses and Silicone RingOct 25, 2018
303 days to decisionK173944 · Product code: **HJK** · Ophthalmic
Source: <https://www.510kdatabase.net/k173944/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lens, Contact, Polymethylmethacrylate, Diagnostic (HJK)
Date received	Dec 26, 2017
Decision date	Oct 25, 2018
Days to decision	303 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Phakos
Location	Montreuil, FR
Contact	J. D. Webb
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](https://accessdata.fda.gov)

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