FDA 510(k) Premarket Notification

**CLEARED**

# K173944 Endocular Viewing Lenses and Silicone Ring

Oct 25, 2018
303 days to decision

K173944 · Product code: **HJK** · Ophthalmic
Source: https://www.510kdatabase.net/k173944/

## SUBMISSION DETAILS

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|---|---|
| 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