

K201892 Ritleng®+ and Ritleng®+ PVPMar 11, 2021
246 days to decisionK201892 · Product code: **OKS** · Ophthalmic
Source: <https://www.510kdatabase.net/k201892/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lacrimal Stents And Intubation Sets (OKS)
Date received	Jul 8, 2020
Decision date	Mar 11, 2021
Days to decision	246 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Fci (France Chirurgie Instrumentation) Sas
Location	Paris, FR
Contact	Thierry Fetick
510(k) history	4 submissions · 4 cleared · 2020-2022

REGULATORY CONSULTANT

Consulting firm	Clinical Research Consultants, Inc.
Contact	Barbara S. Fant

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k201892/> 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 May 27, 2026