FDA 510(k) Premarket Notification

K201892 Ritleng®+ and Ritleng®+ PVP

CLEARED

Mar 11, 2021
246 days to decision

K201892 · 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