FDA 510(k) Premarket Notification

K130375 SELF-RETAINING BICANALICULUS INTUBATON SET II

CLEARED

Dec 4, 2013
293 days to decision

K130375 · Product code: **OKS** · Ophthalmic
Source: https://www.510kdatabase.net/k130375/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lacrimal Stents And Intubation Sets (OKS)
Date received	Feb 14, 2013
Decision date	Dec 4, 2013
Days to decision	293 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Fci Sas (France Chirurgie Instrumentation)**
Location	Cincinnati, OH, US
Contact	BARBARA S FANT
510(k) history	3 submissions · 3 cleared · 2012-2013