FDA 510(k) Premarket Notification

K121142 CRAWFORD BIOCANALICULUS INTUBATION

CLEARED

Aug 9, 2012
115 days to decision

K121142 · Product code: **OKS** · Ophthalmic
Source: https://www.510kdatabase.net/k121142/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lacrimal Stents And Intubation Sets (OKS)
Date received	Apr 16, 2012
Decision date	Aug 9, 2012
Days to decision	115 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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