FDA 510(k) Premarket Notification

K061404 MONO-CRAWFORD NASO-LACRIMAL INTUBATION DEVICE

CLEARED

Aug 7, 2006
80 days to decision

K061404 · Product code: **OKS** · Ophthalmic
Source: https://www.510kdatabase.net/k061404/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lacrimal Stents And Intubation Sets (OKS)
Date received	May 19, 2006
Decision date	Aug 7, 2006
Days to decision	80 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Fci Ophthalmics, Inc.**
Location	Centercille, MA, US
Contact	HILLARD W WELCH
510(k) history	13 submissions · 13 cleared · 1996-2006