

K113536 MASTERKA 40 MASTERKA 35 MASTERKA 30Aug 3, 2012
247 days to decisionK113536 · Product code: **OKS** · Ophthalmic
Source: <https://www.510kdatabase.net/k113536/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Lacrimonal Stents And Intubation Sets (OKS) |
| Date received | Nov 30, 2011 |
| Decision date | Aug 3, 2012 |
| Days to decision | 247 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

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

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