

K964114 DEPUY OPTI-CON AND E-Z SHIELD SYSTEMSMay 6, 1997
203 days to decisionK964114 · Product code: **FXX** · General HospitalSource: <https://www.510kdatabase.net/k964114/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Oct 15, 1996
Decision date	May 6, 1997
Days to decision	203 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Depuy, Inc.
Location	Mchenry, IL, US
Contact	CHERYL HASTINGS
510(k) history	303 submissions · 239 cleared · 1976-2005

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