

K041344 OPEN BORE SYRINGEJul 16, 2004
57 days to decisionK041344 · Product code: **FMF** · General Hospital
Source: <https://www.510kdatabase.net/k041344/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Syringe, Piston (FMF)
Date received	May 20, 2004
Decision date	Jul 16, 2004
Days to decision	57 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Isotis NV
Location	North Attleboro, MA, US
Contact	ELIANE SCHUTTE
510(k) history	8 submissions · 8 cleared · 2000-2007

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