FDA 510(k) Premarket Notification

K041991 ASPIREX - BONE MARROW ASPIRATE KIT

CLEARED

Sep 16, 2004
55 days to decision

K041991 · Product code: **FMF** · General Hospital
Source: https://www.510kdatabase.net/k041991/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Syringe, Piston (FMF)
Date received	Jul 23, 2004
Decision date	Sep 16, 2004
Days to decision	55 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Isotis Orthobiologics, Inc.**
Location	Bilthoven, NL
Contact	PAUL DONER
510(k) history	10 submissions · 10 cleared · 2004-2009

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k041991/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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