FDA 510(k) Premarket Notification

CLEARED

K092023 NAVIJECT SUB2-1P, MODEL: LP604430

Jul 28, 2009
22 days to decision

K092023 · Product code: **MSS** · Ophthalmic
Source: https://www.510kdatabase.net/k092023/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Folders And Injectors, Intraocular Lens (iol) (MSS)
Date received	Jul 6, 2009
Decision date	Jul 28, 2009
Days to decision	22 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Medicel AG**
Location	Hasbrouck Heights, NJ, US
Contact	GEORGE MYERS
510(k) history	6 submissions · 6 cleared · 2004-2025