FDA 510(k) Premarket Notification

K070130 ORBITAL RECONSTRUCTIVE IMPLANT

CLEARED

Apr 19, 2007
93 days to decision

K070130 · Product code: **HPZ** · Ophthalmic
Source: https://www.510kdatabase.net/k070130/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Eye Sphere (HPZ)
Date received	Jan 16, 2007
Decision date	Apr 19, 2007
Days to decision	93 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Becker & Associates Consulting, Inc.**
Location	Washington, DC, US
Contact	CAMPBELL TUSKEY
510(k) history	1 submissions · 1 cleared · 2007-2007