FDA 510(k) Premarket Notification

K170655 Zepto

CLEARED

Jun 2, 2017
91 days to decision

K170655 · Product code: **PUL** · Ophthalmic
Source: https://www.510kdatabase.net/k170655/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Apparatus, Cutting, Radiofrequency, Electrosurgical, Ac-powered (PUL)
Date received	Mar 3, 2017
Decision date	Jun 2, 2017
Days to decision	91 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Mynosys Cellular Devices, Inc.**
Location	Fremont, CA, US
Contact	Dan Marinsik
510(k) history	1 submissions · 1 cleared · 2017-2017