FDA 510(k) Premarket Notification

K120303 CYBERWAND DUAL ACTION ULTRASONIC LITHOTRIPSY SYSTEM

CLEARED

Jun 5, 2012
125 days to decision

K120303 · Product code: **FFK** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k120303/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Lithotriptor, Electro-hydraulic (FFK)
Date received	Feb 1, 2012
Decision date	Jun 5, 2012
Days to decision	125 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Cybersonics, Inc.**
Location	Erie, PA, US
Contact	LORI COLVIN
510(k) history	7 submissions · 7 cleared · 2005-2017