

K142428 Shock Pulse-SE Lithotripsy System CYBERWAND IINov 13, 2014
76 days to decisionK142428 · Product code: **FEO** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k142428/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lithotriptor, Ultrasonic (FEO)
Date received	Aug 29, 2014
Decision date	Nov 13, 2014
Days to decision	76 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k142428/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 1, 2026