

K173590 System 83 Plus Washer/DisinfectorMar 30, 2020
860 days to decisionK173590 · Product code: **FEB** · General Hospital
Source: <https://www.510kdatabase.net/k173590/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accessories, Cleaning, For Endoscope (FEB)
Date received	Nov 21, 2017
Decision date	Mar 30, 2020
Days to decision	860 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Custom Ultrasonics, Inc.
Location	Ivyland, PA, US
Contact	Mario P. Infanti
510(k) history	2 submissions · 2 cleared · 2017-2020

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k173590/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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