

K083598 KARL STORZ VOICE1 SCB R-UI SPEECH CONTROL APPLICATIONMay 29, 2009
175 days to decisionK083598 · Product code: **ODA** · Gastroenterology & Urology
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Central Control Unit (ODA)
Date received	Dec 5, 2008
Decision date	May 29, 2009
Days to decision	175 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	KARL STORZ Endoscopy-America, Inc.
Location	Mchenry, IL, US
Contact	CRYSTAL DIZOL
510(k) history	361 submissions · 361 cleared · 1980-2024

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