

K152794 Cytosponge Cell Collection DeviceApr 12, 2016
197 days to decisionK152794 · Product code: **EOX** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k152794/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Esophagoscope (flexible Or Rigid) (EOX)
Date received	Sep 28, 2015
Decision date	Apr 12, 2016
Days to decision	197 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Covidien, LLC
Location	Mansfield, MA, US
Contact	Clare Santulli
510(k) history	88 submissions · 85 cleared · 2010-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k152794/> 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 3, 2026