

**K181292 PrimeSight™ UNITY 9000 Video Processor,
PrimeSight™ UNITY 9100 Video Processor**Nov 15, 2018
183 days to decisionK181292 · Product code: **EOX** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k181292/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Esophagoscope (flexible Or Rigid) (EOX)
Date received	May 16, 2018
Decision date	Nov 15, 2018
Days to decision	183 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Cogentix Medical, Inc.
Location	Orangeburg, NY, US
Contact	Christa Blaisdell
510(k) history	2 submissions · 2 cleared · 2018-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k181292/> 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 28, 2026