

K113420 RNARETAINMar 16, 2012
119 days to decisionK113420 · Product code: **OZF** · Pathology
Source: <https://www.510kdatabase.net/k113420/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tissue Rna Preservative For Collection, Storage, And Transportation (OZF)
Date received	Nov 18, 2011
Decision date	Mar 16, 2012
Days to decision	119 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Asuragen, Inc.
Location	Austin, TX, US
Contact	Luc Van Hove
Website	http://www.asuragen.com
510(k) history	3 submissions · 1 cleared · 2012-2020

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k113420/> 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 May 14, 2026