

K200970 Self-Contained Biological IndicatorDec 28, 2020
259 days to decisionK200970 · Product code: **FRC** · General Hospital
Source: <https://www.510kdatabase.net/k200970/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Indicator, Biological Sterilization Process (FRC)
Date received	Apr 13, 2020
Decision date	Dec 28, 2020
Days to decision	259 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	True Indicating, LLC
Location	Toledo, OH, US
Contact	Thomas Riha
510(k) history	5 submissions · 5 cleared · 2020-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k200970/> 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 24, 2026