

**K031012 ATTEST RAPID READOUT BIOLOGICAL INDICATOR
FOR EO, MODEL 1294**Oct 16, 2003
199 days to decisionK031012 · Product code: **FRC** · General Hospital
Source: <https://www.510kdatabase.net/k031012/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Indicator, Biological Sterilization Process (FRC)
Date received	Mar 31, 2003
Decision date	Oct 16, 2003
Days to decision	199 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	ATTEST RAPID READOUT BIOLOGICAL INDICATOR FOR EO TEST PACK

APPLICANT

Company	3M Company
Location	White City, OR, US
Contact	CYNTHIA LAMARUCCIOLA
Website	http://www.3m.com/
510(k) history	331 submissions · 322 cleared · 1976-2025

REGULATORY CONSULTANT

Consulting firm	Citech
Contact	ROBERT MOSENKIS

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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