

K241036 Autoclave Indicator TapeDec 17, 2024
245 days to decisionK241036 · Product code: **JOJ** · General Hospital
Source: <https://www.510kdatabase.net/k241036/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Indicator, Physical/chemical Sterilization Process (JOJ)
Date received	Apr 16, 2024
Decision date	Dec 17, 2024
Days to decision	245 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	EO Indicator Tape

APPLICANT

Company	Jiangmen New Era External Use Drug Co., Ltd.
Location	Jiangmen, CN
Contact	Yingxuan Mu
510(k) history	1 submissions · 1 cleared · 2024-2024

REGULATORY CONSULTANT

Consulting firm	Shanghai SUNGO Management Consulting Co., Ltd.
Contact	Ivy Wang

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)**510k Database** - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k241036/> 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 13, 2026