

K191741 Intertape Polymer Inc., Type 1 Bismuth Process Indicator Steam Sterilization TapeAug 2, 2019
32 days to decisionK191741 · Product code: JOJ · General Hospital
Source: <https://www.510kdatabase.net/k191741/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Indicator, Physical/chemical Sterilization Process (JOJ)
Date received	Jul 1, 2019
Decision date	Aug 2, 2019
Days to decision	32 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Intertape Polymer, Inc.
Location	Sarasota, FL, US
Contact	Michael Bryant
510(k) history	1 submissions · 1 cleared · 2019-2019

REGULATORY CONSULTANT

Consulting firm	Highpower Validation Testing & Lab Service's, Inc.
Contact	Gary J. Socola

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/k191741/> 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