

**K190260 STERIZONE(R) VP4 Sterilizer**Jul 19, 2019  
161 days to decisionK190260 · Product code: **PJJ** · General Hospital  
Source: <https://www.510kdatabase.net/k190260/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Two Or More Sterilant Sterilizer (PJJ)
Date received	Feb 8, 2019
Decision date	Jul 19, 2019
Days to decision	161 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Tso3, Inc.</b>
Location	Fairport, NY, US
Contact	Sandy Cliche
510(k) history	10 submissions · 10 cleared · 2006-2019

**REGULATORY CONSULTANT**

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Consulting firm	<b>Biotechnology Transfer, LLC</b>
Contact	Cynthia G. Pritchard

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k190260/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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