

K172191 STERIZONE VP4 SterilizerMay 9, 2018
293 days to decisionK172191 · Product code: **PJJ** · General Hospital
Source: <https://www.510kdatabase.net/k172191/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Two Or More Sterilant Sterilizer (PJJ)
Date received	Jul 20, 2017
Decision date	May 9, 2018
Days to decision	293 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Tso3, Inc.
Location	Fairport, NY, US
Contact	Alexandre Jokic
510(k) history	10 submissions · 10 cleared · 2006-2019

REGULATORY CONSULTANT

Consulting firm	Biotechnology Transfer, LLC
Contact	Cynthia G. Pritchard

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k172191/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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