

**K141580 STERIZONE SELF-CONTAINED BIOLOGICAL INDICATOR**Dec 17, 2014  
187 days to decisionK141580 · Product code: **FRC** · General Hospital  
Source: <https://www.510kdatabase.net/k141580/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Indicator, Biological Sterilization Process (FRC)
Date received	Jun 13, 2014
Decision date	Dec 17, 2014
Days to decision	187 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k141580/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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