

**K210818 TrueCare Biomedix Tamper Evident Cap**Sep 15, 2021  
181 days to decisionK210818 · Product code: **FMF** · General Hospital  
Source: <https://www.510kdatabase.net/k210818/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Piston (FMF)
Date received	Mar 18, 2021
Decision date	Sep 15, 2021
Days to decision	181 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Us Infusion Inc. D/B/A Truecare Biomedix-USA</b>
Location	South Miami, FL, US
Contact	Abbey Kramarz
510(k) history	1 submissions · 1 cleared · 2021-2021

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k210818/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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