

K192382 CapKlenZApr 20, 2020
234 days to decisionK192382 · Product code: **QBP** · General Hospital
Source: <https://www.510kdatabase.net/k192382/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cap, Device Disinfectant (QBP)
Date received	Aug 30, 2019
Decision date	Apr 20, 2020
Days to decision	234 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Star Mountain Medical, Inc.
Location	El Paso, TX, US
Contact	Aaron Chiu
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	Smith Associates
Contact	E. J. Smith

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/k192382/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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