

K192398 Millenium HXOct 3, 2019
30 days to decisionK192398 · Product code: **FIP** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k192398/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Subsystem, Water Purification (FIP)
Date received	Sep 3, 2019
Decision date	Oct 3, 2019
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Mar Cor Purification, Inc.
Location	Minneapolis, MN, US
Contact	Mike Halliday
510(k) history	4 submissions · 4 cleared · 2011-2020

REGULATORY CONSULTANT

Consulting firm	Cantel
Contact	Mark Arnold

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/k192398/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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