

**K133149 BIOPURE HX2 REVERSE OSMOSIS WATER
PURIFICATION SYSTEM**Apr 30, 2014
195 days to decisionK133149 · Product code: **FIP** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k133149/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Subsystem, Water Purification (FIP)
Date received	Oct 17, 2013
Decision date	Apr 30, 2014
Days to decision	195 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k133149/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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