FDA 510(k) Premarket Notification

CLEARED

K142285 AmeriWater Heatsan, 3-phase, 208v, 60hz, AmeriWater Heatsan, 3-phase, 460V, 60hz, Ameriwater Heatsan, 3-phase, 575v, 60hz

Dec 1, 2014
105 days to decision

K142285 · Product code: **FIP** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k142285/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Subsystem, Water Purification (FIP)
Date received	Aug 18, 2014
Decision date	Dec 1, 2014
Days to decision	105 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Ameriwater**
Location	Dayton, OH, US
Contact	Brian R Bowman
510(k) history	11 submissions · 11 cleared · 2000-2014

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k142285/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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