

K180410 Dosis SAMJan 16, 2019
336 days to decisionK180410 · Product code: **MQS** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k180410/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Hemodialysis, Access Recirculation Monitoring (MQS)
Date received	Feb 14, 2018
Decision date	Jan 16, 2019
Days to decision	336 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Dosis, Inc.
Location	Los Altos, CA, US
Contact	Divya Chhabra
510(k) history	1 submissions · 1 cleared · 2019-2019

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/k180410/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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