

K182443 Pristine Hemodialysis CatheterMay 31, 2019
266 days to decisionK182443 · Product code: **MSD** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k182443/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Hemodialysis, Implanted (MSD)
Date received	Sep 7, 2018
Decision date	May 31, 2019
Days to decision	266 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Pristine Access Technologies , Ltd.
Location	Tel-Aviv, IL
Contact	Ron Livne
510(k) history	1 submissions · 1 cleared · 2019-2019

REGULATORY CONSULTANT

Consulting firm	Orly Maor
Contact	Orly Maor

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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