

K192684 HydroPearl MicrospheresJan 22, 2020
118 days to decisionK192684 · Product code: **NOY** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k192684/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Agents, Embolic, For Treatment Of Benign Prostatic Hyperplasia (NOY)
Date received	Sep 26, 2019
Decision date	Jan 22, 2020
Days to decision	118 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	MicroVention, Inc.
Location	Aliso Viejo, CA, US
Contact	Analia Staubly
510(k) history	85 submissions · 85 cleared · 2001-2024

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