

K192644 GM501 SpermAir and GM501 SpermActiveApr 23, 2020
212 days to decisionK192644 · Product code: **MQL** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k192644/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Media, Reproductive (MQL)
Date received	Sep 24, 2019
Decision date	Apr 23, 2020
Days to decision	212 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Hamilton Thorne Incorporated
Location	Beverly, MA, US
Contact	Donald Fournier
510(k) history	2 submissions · 2 cleared · 2020-2020

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