

**K191512 LotusCatheter (Lotus No Balloon Catheter)**May 21, 2020  
349 days to decisionK191512 · Product code: **GBM** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k191512/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent - K
Submission type	Traditional
Device classification	Catheter, Urethral (GBM)
Date received	Jun 7, 2019
Decision date	May 21, 2020
Days to decision	349 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Hakki Medical Technologies, Inc.</b>
Location	Pinellas Park, FL, US
Contact	Shereen Said Hakky
510(k) history	2 submissions · 1 cleared · 2011-2020

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k191512/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 19, 2026