

K101900 HAKKI URINARY CATHETERFeb 7, 2011
215 days to decisionK101900 · Product code: **GBM** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k101900/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Urethral (GBM)
Date received	Jul 7, 2010
Decision date	Feb 7, 2011
Days to decision	215 days
Third-party review	No
Summary / Statement	Summary
Other names	SIZE 14, 16, 18, 20, 22, 24, 26 FRENCH

APPLICANT

Company	Hakki Medical Technologies, Inc.
Location	Pinellas Park, FL, US
Contact	ANDREW ENDAHL
510(k) history	2 submissions · 1 cleared · 2011-2020

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k101900/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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