FDA 510(k) Premarket Notification

K101900 HAKKI URINARY CATHETER

CLEARED

Feb 7, 2011
215 days to decision

K101900 · 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