FDA 510(k) Premarket Notification

K191512 LotusCatheter (Lotus No Balloon Catheter)

CLEARED

May 21, 2020
349 days to decision

K191512 · Product code: **GBM** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k191512/

SUBMISSION DETAILS

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

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