FDA 510(k) Premarket Notification

K172358 Instalief

CLEARED

Jan 10, 2018
160 days to decision

K172358 · Product code: **LKX** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k172358/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Thermal, Hemorrhoids (LKX)
Date received	Aug 3, 2017
Decision date	Jan 10, 2018
Days to decision	160 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Privi Medical Pte, Ltd.**
Location	Singapore, SG
Contact	Prusothman M Sinha Raja
510(k) history	1 submissions · 1 cleared · 2018-2018