FDA 510(k) Premarket Notification

K093537 HANAROSTENT ESOPHAGUS (CCC)

CLEARED

Jun 4, 2010
200 days to decision

K093537 · Product code: **ESW** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k093537/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Prosthesis, Esophageal (ESW)
Date received	Nov 16, 2009
Decision date	Jun 4, 2010
Days to decision	200 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**M.I. Tech Co., Ltd.**
Location	Deerfield, IL, US
Contact	BRANDON CHOI
510(k) history	14 submissions · 11 cleared · 2008-2025