FDA 510(k) Premarket Notification

CLEARED

K180752 Veloxion System, Veloxion Controller Kit, Veloxion Resecting Device Kit, Veloxion Fluid Control Set, Veloxion Saline Pole

Jul 25, 2018
125 days to decision

K180752 · Product code: **HIH** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k180752/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hysteroscope (and Accessories) (HIH)
Date received	Mar 22, 2018
Decision date	Jul 25, 2018
Days to decision	125 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Corinth Medtech, Inc.**
Location	Cupertino, CA, US
Contact	Sandeep Saboo
510(k) history	7 submissions · 7 cleared · 2017-2023