FDA 510(k) Premarket Notification

K192811 BenestaTM Tissue Removal Device

CLEARED

Oct 23, 2020
389 days to decision

K192811 · Product code: **HIH** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k192811/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hysteroscope (and Accessories) (HIH)
Date received	Sep 30, 2019
Decision date	Oct 23, 2020
Days to decision	389 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	**Caldera Medical, Inc.**
Location	Agoura Hills, CA, US
Contact	Vicki Gail
510(k) history	22 submissions · 22 cleared · 2006-2023