FDA 510(k) Premarket Notification

K192534 CrossBay Endometrial Tissue Sampler (ETS)

CLEARED

Mar 25, 2020
191 days to decision

K192534 · Product code: **HHK** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k192534/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Curette, Suction, Endometrial (and Accessories) (HHK)
Date received	Sep 16, 2019
Decision date	Mar 25, 2020
Days to decision	191 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Crossbay Medical**
Location	San Diego, CA, US
Contact	Piush Vidyarthi
510(k) history	3 submissions · 3 cleared · 2019-2020

REGULATORY CONSULTANT

Consulting firm	**Domecus Consulting Services, LLC**
Contact	Cindy Domecus

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov