

K192822 Benesta HysteroscopeSep 9, 2020
344 days to decisionK192822 · Product code: **HIH** · General Hospital
Source: <https://www.510kdatabase.net/k192822/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hysteroscope (and Accessories) (HIH)
Date received	Oct 1, 2019
Decision date	Sep 9, 2020
Days to decision	344 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

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