

K201695 Patent Hemostasis Band (PH Band)Oct 30, 2020
130 days to decisionK201695 · Product code: **DXC** · Cardiovascular
Source: <https://www.510kdatabase.net/k201695/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Clamp, Vascular (DXC)
Date received	Jun 22, 2020
Decision date	Oct 30, 2020
Days to decision	130 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Medical Ingenuities
Location	Wheaton, IL, US
Contact	Richard "Chip" Corrigan
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	Experien Group, LLC
Contact	Valerie Defiesta-Ng

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

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