

K191388 FloPatch (FP110)Jun 21, 2019
28 days to decisionK191388 · Product code: **DPW** · CardiovascularSource: <https://www.510kdatabase.net/k191388/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Flowmeter, Blood, Cardiovascular (DPW) |
| Date received | May 24, 2019 |
| Decision date | Jun 21, 2019 |
| Days to decision | 28 days |
| Third-party review | Yes |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|--|
| Company | Flosonics Medical (R/A 1929803 Ontario Corp.) |
| Location | Sudbury, CA |
| Contact | Joe Eibl |
| 510(k) history | 2 submissions · 2 cleared · 2019-2020 |

REGULATORY CONSULTANT

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|-----------------|--|
| Consulting firm | Regulatory Technology Services, LLC |
| Contact | Mark Job |

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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