

**K181038 CorMatrix Cor Patch (3 cm x 5 cm)(single pack),
CorMatrix Cor Patch (4 cm x 7 cm)(single pack), CorMatrix Cor
Patch (7 cm x 10 cm)(single pack)**Oct 10, 2018
174 days to decisionK181038 · Product code: **PSQ** · Cardiovascular
Source: <https://www.510kdatabase.net/k181038/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Intracardiac Patch Or Pledget, Biologically Derived (PSQ) |
| Date received | Apr 19, 2018 |
| Decision date | Oct 10, 2018 |
| Days to decision | 174 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Cormatrix Cardiovascular, Inc. |
| Location | Sunnyvale, CA, US |
| Contact | Wendy Perreault |
| 510(k) history | 7 submissions · 7 cleared · 2005-2018 |

REGULATORY CONSULTANT

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|-----------------|----------------------------------|
| Consulting firm | New South Regulatory, LLC |
| Contact | Wendy Perreault |

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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