

K051405 REGENSIS PERICARDIAL PATCHAug 31, 2005
92 days to decisionK051405 · Product code: **DXZ** · CardiovascularSource: <https://www.510kdatabase.net/k051405/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Patch, Pledget And Intracardiac, Petp, Ptfе, Polypropylene (DXZ) |
| Date received | May 31, 2005 |
| Decision date | Aug 31, 2005 |
| Days to decision | 92 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k051405/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 27, 2026