

K210405 ProTEC-USA EZDoff GownDec 15, 2021
308 days to decisionK210405 · Product code: **QPC** · General Hospital
Source: <https://www.510kdatabase.net/k210405/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Gown, Non-sterile, Non-isolation, Intended To Provide Moderate Or High Barrier Protection (QPC) |
| Date received | Feb 10, 2021 |
| Decision date | Dec 15, 2021 |
| Days to decision | 308 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Cadillac Products, Inc. |
| Location | Troy, MI, US |
| Contact | Andrew Stone |
| 510(k) history | 1 submissions · 1 cleared · 2021-2021 |

REGULATORY CONSULTANT

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|-----------------|--|
| Consulting firm | Morgan, Lewis, & Bockius, LLP |
| Contact | Dennis Gucciardo |

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k210405/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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