

**K192818 Vertaplex HV High Viscosity Radiopaque Bone Cement**Mar 31, 2020  
182 days to decisionK192818 · Product code: **PML** · Orthopedic  
Source: <https://www.510kdatabase.net/k192818/>**SUBMISSION DETAILS**

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|                       |                                                 |
|-----------------------|-------------------------------------------------|
| Decision              | Substantially Equivalent (Cleared)              |
| Submission type       | Traditional                                     |
| Device classification | Bone Cement, Posterior Screw Augmentation (PML) |
| Date received         | Oct 1, 2019                                     |
| Decision date         | Mar 31, 2020                                    |
| Days to decision      | 182 days                                        |
| Third-party review    | No                                              |
| Summary / Statement   | Summary                                         |
| Other names           | ES2 Augmentable Spinal System                   |

**APPLICANT**

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|----------------|---------------------------------------------------------------|
| Company        | <b>Stryker Corporation</b>                                    |
| Location       | Malwah, NJ, US                                                |
| Contact        | Kristi Ashton                                                 |
| Website        | <a href="http://www.stryker.com/">http://www.stryker.com/</a> |
| 510(k) history | 81 submissions · 81 cleared · 2010-2023                       |

Stryker Corporation is an American multinational medical technology company headquartered in Portage, Michigan. The company develops and markets surgical equipment, neurotechnology, orthopedic implants, and patient safety systems used globally across medical specialties. Stryker has received FDA 510(k) clearances from total submissions between 2010 and 2023. The company's cleared devices span orthopedic surgery, neurosurgery, general and plastic surgery, and ear, nose, and throat specialties. This regulatory record reflects the company's broad portfolio across surgical an...

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