

**K200764 STATSTIX**Oct 15, 2020  
205 days to decisionK200764 · Product code: **MVL** · Dental  
Source: <https://www.510kdatabase.net/k200764/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Cord, Retraction (MVL)             |
| Date received         | Mar 24, 2020                       |
| Decision date         | Oct 15, 2020                       |
| Days to decision      | 205 days                           |
| Third-party review    | No                                 |
| Combination product   | No                                 |
| PCCP authorized       | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Centrix Incorporated</b>           |
| Location       | Shelton, CT, US                       |
| Contact        | Greg Moreau                           |
| 510(k) history | 1 submissions · 1 cleared · 2020-2020 |

**REGULATORY CONSULTANT**

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|-----------------|--------------------|
| Consulting firm | <b>Medtek, LLC</b> |
| Contact         | Roger S Mastrony   |

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k200764/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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