

**K190977 Navina Smart System, Navina Classic System**Nov 22, 2019  
221 days to decisionK190977 · Product code: **KNT** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k190977/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)              |
| Submission type       | Traditional                                     |
| Device classification | Tubes, Gastrointestinal (and Accessories) (KNT) |
| Date received         | Apr 15, 2019                                    |
| Decision date         | Nov 22, 2019                                    |
| Days to decision      | 221 days  |
| Third-party review    | No  |
| Combination product   | No  |
| PCCP authorized       | No  |
| Summary / Statement   | Summary   |

**APPLICANT**

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|----------------|---|
| Company        | <b>Dentsply Sirona</b>  |
| Location       | York, PA, US  |
| Contact        | Karl Nittinger  |
| Website        | <a href="https://www.dentsplysirona.com">https://www.dentsplysirona.com</a> |
| 510(k) history | 65 submissions · 65 cleared · 2016-2026                                     |

Dentsply Sirona is an American dental equipment manufacturer and consumables producer headquartered in York, US. The company markets products in over 120 countries and operates factories across 21 nations. Dentsply Sirona has received FDA 510(k) clearances from total submissions since 2016. Dental devices represent 78% of the company's regulatory submissions, reflecting its core focus on laboratory equipment, specialty products, and consumables including abutments, CAD/CAM blocks, and restorative materials. The company's latest clearance in 2026 demonstrates continued reg...

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k190977/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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