

# K171115 3D Endo Software

Jul 17, 2017  
94 days to decision

K171115 · Product code: **LLZ** · Radiology  
Source: <https://www.510kdatabase.net/k171115/>

## SUBMISSION DETAILS

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)           |
| Submission type       | Traditional                                  |
| Device classification | System, Image Processing, Radiological (LLZ) |
| Date received         | Apr 14, 2017                                 |
| Decision date         | Jul 17, 2017                                 |
| Days to decision      | 94 days                                      |
| Third-party review    | 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...