

**K172224 DTX Studio diagnose**Jan 11, 2018  
170 days to decisionK172224 · Product code: **LLZ** · Radiology  
Source: <https://www.510kdatabase.net/k172224/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)           |
| Submission type       | Traditional                                  |
| Device classification | System, Image Processing, Radiological (LLZ) |
| Date received         | Jul 25, 2017                                 |
| Decision date         | Jan 11, 2018                                 |
| Days to decision      | 170 days                                     |
| Third-party review    | No   |
| Summary / Statement   | Summary                                      |

**APPLICANT**

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|----------------|---|
| Company        | <b>Nobel Biocare AB</b>   |
| Location       | Goteborg, SE  |
| Contact        | Charlemagne Chua  |
| Website        | <a href="https://www.nobelbiocare.com">https://www.nobelbiocare.com</a> |
| 510(k) history | 92 submissions · 92 cleared · 2002-2026                                 |

Nobel Biocare AB is a medical device manufacturer based in Goteborg, Sweden. The company specializes in implant systems and related technologies for oral and maxillofacial applications. Nobel Biocare AB has received FDA 510(k) clearances from total submissions since 2002. The company's regulatory portfolio is dominated by Dental devices, which account for approximately 86% of submissions. Recent clearances include implant systems, abutments, and digital imaging software, with the latest FDA 510(k) clearance in 2026, demonstrating continued regulatory activity. The company...

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