

**K222619 Ensmile**Mar 16, 2023  
198 days to decisionK222619 · Product code: **NXC** · Dental  
Source: <https://www.510kdatabase.net/k222619/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Aligner, Sequential (NXC)          |
| Date received         | Aug 30, 2022                       |
| Decision date         | Mar 16, 2023                       |
| Days to decision      | 198 days                           |
| Third-party review    | No                                 |
| Combination product   | No                                 |
| PCCP authorized       | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Ensmile Pvt, Ltd.</b>              |
| Location       | Johar Town, PK                        |
| Contact        | Mirza Gohar Rehman                    |
| 510(k) history | 1 submissions · 1 cleared · 2023-2023 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k222619/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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