FDA 510(k) Premarket Notification

# K211872 PiezoImplant System

**CLEARED**

Oct 12, 2022
482 days to decision

K211872 · Product code: **NRQ** · Dental
Source: https://www.510kdatabase.net/k211872/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Blade-form Endosseous Dental Implant (NRQ) |
| Date received | Jun 17, 2021 |
| Decision date | Oct 12, 2022 |
| Days to decision | 482 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Rex Implants, Inc.** |
| Location | Columbus, OH, US |
| Contact | Giuseppe Vercellotti |
| 510(k) history | 1 submissions · 1 cleared · 2022-2022 |

## REGULATORY CONSULTANT

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|---|---|
| Consulting firm | **Backroads Consulting** |
| Contact | Karen E Warden |

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