

K163251 Life Essence Universal Porcelain SystemAug 4, 2017
259 days to decisionK163251 · Product code: **EIH** · DentalSource: <https://www.510kdatabase.net/k163251/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Powder, Porcelain (EIH) |
| Date received | Nov 18, 2016 |
| Decision date | Aug 4, 2017 |
| Days to decision | 259 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Blue Sky Bio |
| Location | Irvine, CA, US |
| Contact | ALBERT ZICKMANN |
| 510(k) history | 5 submissions · 5 cleared · 2000-2018 |

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