

K031813 OSSATURA DENTALAug 20, 2004
435 days to decisionK031813 · Product code: **LYC** · DentalSource: <https://www.510kdatabase.net/k031813/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Bone Grafting Material, Synthetic (LYC) |
| Date received | Jun 12, 2003 |
| Decision date | Aug 20, 2004 |
| Days to decision | 435 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Isotis NV |
| Location | North Attleboro, MA, US |
| Contact | MARY MCNAMARA-CULLINANE |
| 510(k) history | 8 submissions · 8 cleared · 2000-2007 |

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