FDA 510(k) Premarket Notification

# K042829 DBX STRIP

**CLEARED**

Jan 13, 2006
458 days to decision

K042829 · Product code: **MBP** · Orthopedic
Source: https://www.510kdatabase.net/k042829/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Filler, Bone Void, Osteoinduction (w/o Human Growth Factor) (MBP) |
| Date received | Oct 12, 2004 |
| Decision date | Jan 13, 2006 |
| Days to decision | 458 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Musculoskeletal Transplant Foundation** |
| Location | Edison, NJ, US |
| Contact | KAREN HARDWICK |
| 510(k) history | 24 submissions · 24 cleared · 2004-2019 |

**510k Database** - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k042829/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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