FDA 510(k) Premarket Notification

# K220336 Mg-PSZ Ceramic Femoral Head

**CLEARED**

Sep 30, 2022
235 days to decision

K220336 · Product code: **LPH** · Orthopedic
Source: https://www.510kdatabase.net/k220336/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Prosthesis, Hip, Semi-constrained, Metal/polymer, Porous Uncemented (LPH) |
| Date received | Feb 7, 2022 |
| Decision date | Sep 30, 2022 |
| Days to decision | 235 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Theken Companies** |
| Location | Akron, OH, US |
| Contact | Garrett Spurgeon |
| 510(k) history | 1 submissions · 1 cleared · 2022-2022 |

## REGULATORY CONSULTANT

| | |
|---|---|
| Consulting firm | **BioVera, Inc.** |
| Contact | Robert A. Poggie |

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