FDA 510(k) Premarket Notification

# K110807 ABG II MONOLITHIC HIP STEM

**CLEARED**

May 25, 2011
63 days to decision

K110807 · Product code: **MAY** · Orthopedic
Source: https://www.510kdatabase.net/k110807/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Prosthesis, Hip, Semi-constrained, Metal/ceramic/polymer, Cemented Or Non-porous Cemented, Osteophilic Finish (MAY) |
| Date received | Mar 23, 2011 |
| Decision date | May 25, 2011 |
| Days to decision | 63 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Stryker Corp.** |
| Location | Mchenry, IL, US |
| Contact | STEPHANIE FITTS |
| 510(k) history | 124 submissions · 121 cleared · 1976-2023 |

Stryker Corp. is an American multinational medical technology company headquartered in Portage, Michigan. The company develops and markets surgical equipment, implants, and patient safety technologies used globally across multiple medical specialties. Stryker has received FDA 510(k) clearances from total submissions since its first clearance in 1976. The company maintains active regulatory engagement, with its latest clearance in 2023. Its product portfolio spans orthopedic devices, neurosurgical implants, surgical instruments, and endoscopy systems, reflecting a broad pr...

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Device record: https://www.510kdatabase.net/k110807/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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