



Press Release

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3D Systems Announces FDA 510(k) Clearance Expanding VSP® Orthopedics Indications to Include Skeletally Mature Adolescents

*Removes Key Adoption Barriers in Pediatric/Adolescent Oncology and
Deformity Market*

ROCK HILL, South Carolina, December 15, 2025 – 3D Systems (NYSE: DDD) today announced that the U.S. Food and Drug Administration has granted 510(k) clearance expanding the indications for its VSP® Orthopedics virtual surgical planning and patient-specific instrumentation platform to include skeletally mature adolescents of normal bone stature, in addition to adults.

Key Investment Highlights

- **Immediate commercial acceleration:** Eliminates case-by-case compassionate-use approvals and hospital IRB reviews previously required for these adolescent patients, streamlining workflows and converting off-label usage into standard, reimbursable procedures at leading centers.
- **Targets high-acuity, underserved segment:**
 - Over 1,200 new annual U.S. cases of osteosarcoma and Ewing sarcoma in patients under 20 (American Cancer Society, SEER estimates).
 - Additional 2,600 primary bone cancer cases in young adults (20–39) now fully in-scope.
 - Thousands of complex lower-limb osteotomies and reconstructive procedures annually for congenital, developmental, and trauma-related deformities in adolescents.

- **Strong, Sustainable Financial Model:** VSP Orthopedics cases generate service fees for virtual planning combined with revenue from patient-specific 3D-printed anatomic models and single-use surgical guides produced on 3D Systems' additive manufacturing platforms. Resulting revenues contribute to the strong, double-digit annual growth rates and highly accretive gross margins associated with 3D Systems' Med Tech business.
- **Strengthened competitive moat:** 3D Systems is the only provider with FDA-cleared VSP solutions spanning craniomaxillofacial, orthopedics, and now expanded adolescent applications, with a total of over 400,000 total patient-matched cases and devices delivered to date.
- **Favorable reimbursement:** Procedures covered under existing DRG/CPT codes for tumor resection, osteotomy, and reconstruction—no changes required.

Ben Johnson, senior vice president of medical technology at 3D Systems commented, "This regulatory clearance removes a significant friction point for adoption in the pediatric/adolescent orthopedic oncology segment. Surgeons at leading centers have been using off-label or compassionate use solutions for years; this decision immediately converts those cases into routine clinical practice and opens the U.S. adolescent bone sarcoma and deformity market to our platform. We are thrilled to now offer these solutions to an expanded and underserved patient population."

This regulatory clearance further supports 3D Systems' focus on high-margin personalized healthcare solutions amid ongoing segment optimization efforts. Continuing expanded indications provides a meaningful tailwind for sustaining double-digit average annual growth in the Healthcare segment, driven in part by accelerated adoption in this discrete, high-value market.

About 3D Systems

For nearly 40 years, Chuck Hull's curiosity and desire to improve the way products were designed and manufactured gave birth to 3D printing, 3D Systems, and the additive manufacturing industry. Since then, that same spark continues to ignite the 3D Systems team as we work side-by-side with our customers to change the way industries innovate. As a full-service solutions partner, we deliver industry-leading 3D printing technologies, materials and software to high-value markets such as medical and dental; aerospace, space and defense; transportation and motorsports; AI infrastructure; and durable goods. Each application-specific solution is powered by the expertise and passion of our employees who endeavor to achieve our shared goal of Transforming Manufacturing for a Better Future.

Forward-Looking Statements

Certain statements made in this release that are not statements of historical or current facts are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause the actual results, performance or achievements of the company to be materially different from historical results or from any future results or projections expressed or implied by such forward-looking statements. In

many cases, forward-looking statements can be identified by terms such as "believes," "belief," "expects," "may," "will," "estimates," "intends," "anticipates" or "plans" or the negative of these terms or other comparable terminology. Forward-looking statements are based upon management's beliefs, assumptions, and current expectations and may include comments as to the company's beliefs and expectations as to future events and trends affecting its business and are necessarily subject to uncertainties, many of which are outside the control of the company. The factors described under the headings "Forward-Looking Statements" and "Risk Factors" in the company's periodic filings with the Securities and Exchange Commission, as well as other factors, could cause actual results to differ materially from those reflected or predicted in forward-looking statements. Although management believes that the expectations reflected in the forward-looking statements are reasonable, forward-looking statements are not, and should not be relied upon as a guarantee of future performance or results, nor will they necessarily prove to be accurate indications of the times at which such performance or results will be achieved. The forward-looking statements included are made only as of the date of the statement. 3D Systems undertakes no obligation to update or review any forward-looking statements made by management or on its behalf, whether as a result of future developments, subsequent events or circumstances or otherwise.