Hyprevention Y-STRUT Hip Implant granted as a Breakthrough Device by the FDA

Hyprevention has developed the STRUTPLASTY® Technology to reinforce bones weakened by osteoporosis or cancer. The Y-STRUT Hip Implant is part of STRUTPLASTY®.

NEW YORK, NY, UNITED STATES, May 27, 2025 /EINPresswire.com/ -- Hyprevention has developed the STRUTPLASTY® Technology to reinforce bones weakened by osteoporosis or cancer. The Y-STRUT Hip Implant, part of STRUTPLASTY®, has been recognized as a Breakthrough Device by the FDA.

The FDA Breakthrough Devices Program is a voluntary initiative for certain medical devices that offer more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions. The innovative Y-STRUT Hip Implant has been approved for the following indications:

- Oncology: For adult patients with cancer presenting with bone metastasis or lesions in the proximal femur. It is intended for percutaneous prophylactic fixation of the proximal femur in patients with impending pathological fractures.
- Orthopedics-Traumatology: For contralateral percutaneous internal fixation of the proximal femur in osteoporotic patients with a low-energy per trochanteric fracture on one side and at risk of a new hip fracture.

Cecile Vienney Vivez, the CEO and founder of Hyprevention, has 25 years of experience in developing innovative orthopedic products at Stryker and in start-ups like Vexim (now part of Stryker) and Hyprevention. She stated, “Hip fracture prevention is crucial for the elderly and patients with tumors in the proximal femur to ensure the best quality of life. Y-STRUT was the first product developed at Hyprevention, as the hip is one of the most common sites of bone fractures, with the spine. After marketing the product in Europe, we are excited to introduce the Y-STRUT Technology in the United States. Clinical studies conducted in France and Belgium have demonstrated the safety and efficacy of our product, making numerous patients happy and autonomous. Receiving FDA Breakthrough Designation for our hip device is a major recognition for the company and the team.”

Hyprevention was established in 2010 in France to develop STRUTPLASTY® Technology. In 2024, Hyprevention Inc., incorporated in Delaware, became the parent company of the group. Hyprevention is building a product portfolio with its STRUTPLASTY® Technology. The V-STRUT Vertebral Implant, indicated for treating vertebral fractures, is already available in the US market

following two FDA 510(k) clearances. This product provides the best clinical outcomes in terms of preventing subsequent and adjacent fractures compared to its competitors. With the new Y-STRUT Hip Implant, the company confirms its ability to meet regulatory requirements and address the clinical needs of patients and physicians.

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