



Safe Group announces FDA 510(k) clearance for SpineUp's Frida solution

Fleurieux-sur-l'Arbresle - France - June 5, 2025 at 6 p.m. Safe Group, a leading player in the field of medical devices for spine surgery, is pleased to announce that Frida, the innovative cervical plate developed by SpineUp, has received 510(k) clearance from the Food and Drug Administration (FDA). This clearance marks a crucial step in SpineUp's expansion into the North American market, and testifies to its ongoing commitment to providing cutting-edge medical solutions.

Frida is a new-generation cervical plate offering high adaptability with a multiplicity of plate and screw sizes. Thanks to this technology, healthcare professionals will be able to offer more personalized treatments, tailored to the specific needs of surgeons and their patients.

FDA 510(k) clearance is the result of several years of research and development. This certification attests to the safety and efficacy of the Frida solution, which complies with the FDA's strict standards and is due to be marketed by the end of the year.

« In view of the merger of Safe's subsidiaries with SpineUp, we are delighted that this authorization has been granted and that SpineUp has taken a major step forward, validating the company's commitment to innovation and improving patient care, » says Victor Humberdot, Chairman of Safe Group.

“This new step heralds new business opportunities for SpineUp and its subsidiaries Safe Orthopaedics and Safe Medical, increased synergy and a stronger foothold in the U.S.” comments Philippe Laurito, President of SpineUp Inc.

About Safe Group

Safe Group is a French medical technology group that brings together Safe Orthopaedics, a pioneer in ready-to-use technologies for spine pathologies, and Safe Medical (formerly LCI Medical), a medical device subcontractor for orthopedic surgeries. The group employs approximately 100 people.

Safe Orthopaedics develops and manufactures kits combining sterile implants and ready-to-use instruments, available at any time to the surgeon. These technologies are part of a minimally invasive approach aimed at reducing the risks of contamination and infection, in the interest of the patient and with a positive impact on hospitalization times and costs. Protected by 15 patent families, SteriSpine™ kits are CE marked and FDA approved. Safe Orthopaedics has subsidiaries in the United Kingdom, Germany, the United States.

For more information: www.safeorthopaedics.com

Safe Medical produces implantable medical devices and ready-to-use instruments. It has an innovation center and two production sites in France and in Tunisia, offering numerous industrial services: industrialization, machining, finishing and sterile packaging.

For more information: www.safemedical.fr



Contacts

SAFE GROUP

investors@safeorthopaedics.com

AELYON ADVISORS

safe@aelyonadvisors.fr