

SMAIO receives FDA 510(k) clearance for "K-rod", its patient-specific union rod

Lyon (France), June 15, 2022 – 6 pm CEST – SMAIO (Software, Machines and Adaptative Implants in Orthopaedics – Euronext Growth Paris ISIN: FR0014005180 / Ticker: ALSMA, eligible for PEA-PME equity savings plans), a French player specialized in complex spine surgery with a global offer comprising software, adaptative implants and related services, today announced that it has received FDA 510(k) clearance for "K-rod", its patient-specific rod.

K-rod union rods are patient specific, respecting the patient's anatomy, thanks to the accurate 3D modeling undertaken with SMAIO's KEOPS Balance Analyzer 3D software. Combined with the Kheiron posterior spinal fixation system, they enable the strict alignment of the spine on the rod. The K-rod range has been marketed in Europe since June 2019, and obtaining this 510(k) clearance allows SMAIO to offer these innovative rods to North American surgeons for the first time.

Philippe ROUSSOULY, CEO of SMAIO, comments: *"In 2012, SMAIO was the first company in the world to unveil spinal realignment surgical planning software capable of simulating the compensations of the patient's imbalances at pelvic and thoracic level. Today, on the strength of the experience acquired through thousands of cases of surgical planning undertaken for hundreds of surgeons with the majority of implantable devices that exist on the market, SMAIO is able to provide its own holistic solution combining planning, execution and evaluation of results via its i-kontrol platform. Thanks to the 510(k) clearance obtained for "K-rod", our solution can now be offered in its entirety in North American medical centers. Indeed, 510(k) clearance for this patient-specific rod technology, following that received for the Balance Analyzer 3D surgery planning software last month and the Kheiron spinal fixation system in October 2020, will enable us to accelerate the distribution of the i-kontrol holistic solution in the United States, in line with our global strategy, which aims to make spine surgery more effective, safer and more predictable".*

Upcoming financial events:

- **Shareholders' AGM:** June 20, 2022
- **Publication of H1 2022 sales:** July 12, 2022, after market

About SMAIO

A precursor in the use of clinical data and imaging of the spine, SMAIO designs global solutions for spine surgery specialists. The Company has recognized expertise thanks to KEOPS, its Big Data management software that has become a global reference with more than 100,000 patient cases documented.

SMAIO offers spine surgeons a comprehensive platform, I-Kontrol, incorporating planning, implants and related services, enabling them to treat spinal pathologies in a safe, effective and lasting way.

SMAIO is positioned at the forefront of innovation with the ambition of providing surgeons with the first active robotic solution enabling a high level of performance and repeatability to be achieved.

Based in Lyon, France, SMAIO benefits from the skill and expertise of more than 30 highly specialized staff.

For further information, please visit our website: www.smaio.com

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