SmartCella

Press release **Stockholm September 17, 2026**

The Extroducer® 2.0 receives 510(k) clearance by the US FDA

SmartCella Holding AB ("SmartCella") today announces that the updated 2.0 version of the Extroducer® has received 510(k) clearance by the US Food and Drug Administration (FDA). The clearance maintains the same indications as the previous version, namely for use in the peripheral vasculature to infuse diagnostic and therapeutic solutions into the extravascular space, including in abdominal tissues associated with the peripheral vasculature.

SmartCella is a global drug delivery company pioneering innovative delivery solutions for targeted therapies. The main technology, the Extroducer®, is a modality-agnostic endovascular delivery device designed for localized delivery to hard-to-reach organs, tumors, and tissues. The Extroducer® was FDA 510(k)-cleared already in 2022 for use in peripheral (including abdominal) tissues to inject diagnostic and therapeutic solutions. Obtaining 510(k) clearance for the updated version is a strong validation of its safety and performance from the FDA, the world's most significant regulatory agency. The Extroducer® is currently in clinical investigation for additional indications.

Niklas Prager, CEO, comments: "Receiving 510(k) clearance for the updated version of the Extroducer® is an important step forward for SmartCella. It allows us to deepen our commitment even further to the US market, the world's largest and most influential life science market. 510(k) clearance also serves as a quality stamp that strengthens our position across our markets worldwide, making this a great advancement both from a commercial perspective and for patients with diseases or diagnoses where targeted delivery is a challenge."

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About SmartCella
SmartCella is a global drug delivery company pioneering innovative delivery solutions for targeted therapies. The main technology, the Extroducer®, is a modality-agnostic endovascular delivery device designed for localized delivery to hard-to-reach organs, tumors, and tissues. The Extroducer® is FDA 510(k)-cleared for use in peripheral (including abdominal) tissues to inject diagnostic and therapeutic solutions into the extravascular space. It is currently in clinical investigation for additional indications. SmartCella commercializes the Extroducer® through licensing agreements with global biotech and pharma companies, enabling broad application across all development phases. The company also offers a proprietary stem cell platform for the delivery of mRNA therapeutics, featuring a proof-of-concept program focused on Osteoarthritis.

Founded in 2014, SmartCella is built on world-class research from Sweden's Karolinska Institutet.

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