FOR IMMEDIATE RELEASE

ACell Announces Additional Clearances for Gentrix Surgical Matrix Family of Products

Columbia, MD — (April 3, 2019) – ACell, Inc. today announced that it has received a new 510(k) clearance from the US Food and Drug Administration (FDA) covering several devices in its Gentrix® Surgical Matrix suite of products.

The clearance updates the indications for use for Gentrix Surgical Matrix, Gentrix Surgical Matrix Thin, and Gentrix Surgical Matrix Plus, adding important new claims to the product labeling. Notably, these devices were shown to minimize unwanted attachment to surrounding visceral tissue. Further, ACell gained the specific indication for use of these three Gentrix devices in laparoscopic applications. Finally, ACell obtained clearance for a new hernia device configuration specifically indicated for reinforcement of hiatal hernia repairs.

“ACell continues to expand its presence in the hernia marketplace,” said Patrick McBrayer, President and CEO. “This milestone from the FDA is another strategic building block in our objective to meet the needs of clinicians and patients with safe, cost-efficient, and clinically effective devices for complex hernia repair.”

“These clearances are especially impactful in supporting the use of Gentrix Surgical Matrix devices in minimally invasive hernia repairs. Surgeons performing such repairs know that if they heal with the formation of excess scar tissue, they are at risk for devastating complications, potential re-operations, and increased healthcare costs,” said Hazem Elariny, MD, Medical Director. “Additionally, if a surgeon chooses to utilize a product in the intraperitoneal fashion, the demonstrated minimal attachment to surrounding tissue makes Gentrix an ideal option in these cases.”

The pre-clinical data used to support the new clearances will be presented in two posters at the Society of American Gastrointestinal and Endoscopic Surgeons Annual Meeting in Baltimore, Maryland April 3-6. The first poster describes data that shows the minimization of tissue attachments to Gentrix when in contact with viscera. The study assessed the ability of two surgical grafts – Gentrix and SIS (small intestinal submucosa) – to minimize tissue attachments to the device in a rabbit model of intraperitoneal device placement, and concluded that the Gentrix devices performed similar or better than the SIS grafts. A second poster will also be presented to describe the performance of Gentrix in a preclinical model of laparoscopic hiatal hernia repair.

About ACell, Inc.
ACell, Inc. is a leading regenerative medicine company focused on the development, manufacturing, and commercialization of medical devices for surgical soft tissue repair and wound management. ACell is committed to becoming and remaining an innovative leader in regenerative medical technology, offering superior healing options for doctors and patients. ACell is a privately held company and operates manufacturing facilities in Columbia, MD and Lafayette, IN.

About Gentrix Surgical Matrix
Gentrix® Surgical Matrix Thin (3-layer) is intended for implantation to reinforce soft tissue where weakness exists in patients requiring urological, gastroenterological, or plastic & reconstructive surgery. Reinforcement of soft tissue within urological, gastroenterological, and plastic & reconstructive surgery includes, but is not limited to, the following open or laparoscopic procedures: hernia and body wall repair, colon and rectal prolapse repair, tissue repair, and esophageal repair. The Gentrix® Surgical Matrix Thin (3-layer) minimizes tissue attachment to the device in case of direct contact with viscera.
Gentrix® Surgical Matrix and Gentrix® Surgical Matrix Plus (6-layer and 8-Layer) are intended for implantation to reinforce soft tissue where weakness exists in patients requiring gastroenterological or plastic & reconstructive surgery. Reinforcement of soft tissue within gastroenterological and plastic & reconstructive surgery includes, but is not limited to, the following open or laparoscopic procedures: hernia (e.g.: hiatal/diaphragmatic) and body wall repair, colon and rectal prolapse repair, tissue repair, and esophageal repair. The Gentrix® Surgical Matrix and Gentrix® Surgical Matrix Plus (6-layer and 8-Layer) minimizes tissue attachment to the device in case of direct contact with viscera.

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