



NeXtGen Biologics Receives FDA 510(k) Clearance for its Novel Dermal Wound Matrix

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GAINESVILLE, Fla., October 22, 2018 — NeXtGen Biologics, Inc., announced it has received 510(k) clearance from the U.S. Food and Drug Administration to market NeoMatriX<sup>®</sup>, a novel dermal wound matrix developed for the management of a variety of acute and chronic wounds.

The FDA decision allows NeXtGen Biologics to advance its product line for marketing in the United States. “FDA clearance for NeoMatriX is a pivotal milestone, allowing NeXtGen to move forward in providing physicians with a novel platform solution to treat patients who suffer from a wide variety of wounds including surgical wounds,” said Jonelle Toothman, NeXtGen Biologics CEO.

Chronic wounds, described as taking from four weeks to more than three months to heal, affect more than 6 million U.S. patients each year — a number estimated to grow by 2020 with an aging population, according to the National Institutes of Health.

Developed for the U.S. surgical wound market, NeoMatriX sheets, produced in varying sizes and stored at room temperature are indicated for the management of acute and chronic wounds, full and partial thickness, including surgical wounds and burns.

Derived from the dermis of an Axolotl amphibian species, the NeoMatriX patch is applied to human wounds similar to ECM technology developed previously from pig, cow or human tissue.

More than \$25 billion a year is spent by the U.S. health-care system in treating wound-related complications that often cause pain, disability and depression, and may lead to lower-extremity amputations or even death.

The NeXtGen Biologics technology, derived from a neotenic xenograft source, provides new options for surgeons facing complex conditions in surgical and wound care centers nationally.

#### **About NeXtGen Biologics, Inc.**

NeXtGen Biologics is an innovative medical device company developed to advance wound care. Currently, NeXtGen is developing a novel extracellular matrix (ECM) product with a pipeline of new technologies. Leveraging a world-class team with expertise in medical devices and breakthrough tissue technologies, the company will offer surgeons unique platform solutions that are designed to be transformative for patients and the goal of better managing a myriad of complex conditions seen in general surgery, trauma, cardiovascular diseases, neurosurgery, orthopedics and ophthalmology.

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