

PRINTERPREZZ RECEIVES 510(k) CLEARANCE FOR NEW FAMILY OF 3D PRINTED SPINE DEVICES

PrinterPrezz today announced FDA clearance of the company's 510(k) for the PrinterPrezz GAIA™ Lumbar Interbody Fusion Device (LIFD) family of spine implants

FREMONT, CA, UNITED STATES, October 13, 2020 /EINPresswire.com/ -- [PrinterPrezz, Inc.](#), a



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Dr. Alan Dang, Chief Medical Officer of PrinterPrezz

trailblazer in medical polymer and metal 3D printing, nanotechnologies and implant design, today announced the U.S. Food and Drug Administration (FDA) clearance of the company's 510(k) for the PrinterPrezz GAIA™ Lumbar Interbody Fusion Device (LIFD) family of spine implants as a reference platform for future medical device innovators. The first implant systems announced today under the GAIA™ platform include the Astraeus ALIF, Themis TPLIF, and Prometheus PLIF systems. Market introduction plans have not yet been finalized.

"The products announced today represent our cumulative learnings in medical device design, additive manufacturing processes, non-active implantable medical device (NAIMD)

testing, cleaning, packaging & sterilization, and quality management," said Shri Shetty, CEO of PrinterPrezz. "What makes GAIA™ a true reference platform, and PrinterPrezz a true medical device foundry, is that our customers have access to the array of technologies developed and validated during the GAIA™ program for their own product lines. Experienced customers benefit from our 3D print and design optimizations that help reduce manufacturing costs, while small, and mid-size customers may find benefit leveraging our FDA documentation."

The Astraeus, Themis and Prometheus lumbar interbody systems are manufactured in titanium (Ti6Al4V-ELI) using Laser Powder Bed Fusion technology. Some of the designs leverage technologies jointly developed at the San Francisco VA Health Center and University of California (UCSF). This licensing deal was negotiated with UCSF Innovation Ventures' Office of Technology Management which leads licensing and business development efforts on behalf of the university in collaboration with the VA.

Dr. Alan Dang, Chief Medical Officer of PrinterPrezz, stated, "GAIA™ represents a core technology platform that showcases both PrinterPrezz's existing technology leadership in additive manufacturing, and serves as the foundation for PrinterPrezz's ongoing research and development in support of our customers."

About PrinterPrezz

PrinterPrezz's mission is to bring more ideas for innovative medical devices to market faster, connecting medicine and manufacturing to become the first Medifactory™ company in the world. By developing advanced medical devices using processes that combine expertise in 3D printing, orthopaedics, semiconductor and nanotechnologies, PrinterPrezz's ultimate goal is to

provide medical solutions that enable people to enjoy active lives longer. PrinterPrezz's ecosystem aims to solve challenges for various parts of the medical innovation value chain by providing prototyping, development, and manufacturing services to create life-enhancing medical devices. PrinterPrezz provides customers with access to a variety of 3D printing machines, 3D manipulation software, and 3D scanners as well as advanced manufacturing processes, and surgeon education programs. Medical solutions created by PrinterPrezz are designed to enable more people to live happier and more gratifying lives. For additional information about the company, please visit www.printerprezz.com.

The information stated above was prepared by PrinterPrezz, Inc. to report on research conducted on its product and reflects solely the opinion of PrinterPrezz, Inc. Nothing in this statement shall be construed to imply any support or endorsement of PrinterPrezz, Inc., or any of its products, by The Regents of the University of California, its officers, agents and employees.

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Teresa Thuruthiyil
PrinterPrezz, Inc.
+1 415-577-9222
[email us here](#)



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