

Earlens Corporation Ramps Up Production of Hearing Aid with 3D Printing Help from iBASEt Solumina Software

by Clare Scott, Sep 7, 2016

3D printing has improved the lives of people with disabilities in more ways than perhaps any other technology. Lately, 3D printed inventions for the visually impaired have been in the spotlight, including 3D printed [ultrasound images](#), tactile [data systems](#), and [tactile picture books](#), just to name a few. Less commonly seen is 3D printing for the hearing impaired – but that doesn't mean that researchers and product developers aren't working hard at inventing devices to help the deaf and partially deaf to regain their hearing.

The California-based [Earlens Corporation](#) has developed an incredible new type of hearing aid that uses light, of all things, to enhance hearing. The Earlens Hearing Aid is like a contact lens for the ear, attaching directly to the eardrum through surface tension – the same way a contact lens adheres to the eye. The device consists of three parts: a photon processor, a light tip, and a custom-fitted lens, which is placed in the ear by an ear, nose and throat specialist. The photon processor, which rests behind the ear, transmits sound waves to the light tip, which converts the sound into non-visible light. The light, in turn, signals the lens to activate the wearer's natural hearing system. It sounds unbelievable, but it works. According to Earlens, the device delivers a broader range of sound frequency than any other hearing aid on the market. To get a visual of how it works, watch [this video](#).

At the end of 2015, the FDA granted Earlens a De Novo classification, allowing them to begin marketing the device. The company is now ramping up production, using 3D printing to speed up the manufacturing process and improve design flexibility. To support production, the company is turning to [iBASEt](#), producer of software solutions for a diverse range of industries including aerospace and defense, electronics, medical devices, and more. iBASEt's Solumina software includes their Manufacturing Execution Systems and Operations Management (MES/MOM) suites, plus Maintenance, Repair, and Overhaul (MRO) and Enterprise Quality Management Systems (EQMS). Earlens will be implementing the Solumina MES software in their Menlo Park headquarters to help them manage production, quality control and cost efficiency.

“We are excited to work with iBASEt to put in place an innovative technology manufacturing infrastructure,” said Mark Bishop, VP of Operations of Earlens. “We believe it is a smart move for us to implement an MES/QMS solution now, in the early stages of our business, so that we can rapidly scale production to meet growing demand for our product and keep pace with design changes and improvements.”

The Solumina software will reduce batch file administration efforts of electronic device history records while maintaining complete records of products manufactured, ensuring quality and compliance with 21 CFR Part 11 and Part 820. Solumina is also expected to increase product yield and enable supervisors and office personnel to better monitor the status of work orders.

“Additive manufacturing, using 3D printing technology, is a fundamentally new approach that offers manufacturers a number of advantages over traditional methods for better design flexibility, time to market and cost control,” said Vic Sial, President of iBASEt. “We appreciate the confidence Earlens has placed in iBASEt by choosing our software and team of experts to put in place the innovative manufacturing infrastructure the company needs to manage production, streamline operations and meet changing design and regulatory requirements.”