



Artificial Iris of HumanOptics Received FDA Approval

Approval process under Breakthrough Devices Program completed within only six months / Only FDA-approved artificial iris in the U.S. / Broad access gained to a highly attractive market

Erlangen, May 31, 2018 – The ARTIFICIALIRIS prosthesis of HumanOptics AG (ISIN DE000A1MMCR6) – a leading technology company in manufacturing high-quality implants for eye surgery – received FDA approval.

Dr. Pierre Billardon, CEO of HumanOptics AG, is very pleased to have been granted regulatory approval: “Our custom-made iris implant is a unique product with extremely high benefits to patients. That is why our ARTIFICIALIRIS was accepted into the FDA’s Breakthrough Devices Program on December 1, 2017. Just a few months later, we have already received approval for it. The ARTIFICIALIRIS is at present the only product of this kind that is approved for the highly attractive U.S. market and addresses this currently unmet medical need in that market.”

The ARTIFICIALIRIS is used to treat patients who have partially or completely lost their iris as the result of an accident or who were born without an iris. This affliction is very burdensome to patients in their social lives and in other situations. Furthermore, it often comes with a whole range of additional medical complications, such as light sensitivity, loss of vision, or an above-average risk of glaucoma and cataract formation.

Every ARTIFICIALIRIS is customized by HumanOptics to match the original appearance of the patient’s iris. It is made of a flexible silicon material that is inserted into the eye using a microsurgical technique – making it well tolerated. This ensures both the patient’s clinical and aesthetic needs are met, achieving a high level of satisfaction.

HumanOptics AG has already established an excellent reputation for itself in this highly specialized market for optical surgery in the U.S. As part of a medical study begun in 2013, more than 600 successful operations have already been performed at 12 hospitals throughout the country. The market potential for our product is around 150 hospitals and 1,000 to 1,500 patients per year.

Dr. Billardon therefore expects this product to offer high potential for revenue and income: “We predict that the artificial iris will become a top product for our company over the medium term. Many of our current surgeons already have waiting lists of patients who need our artificial iris but were unable to be treated during the study. Besides the



significant market potential in the U.S., FDA approval will also boost our image in the European markets, where we are already allowed to offer this product.”

Company Profile:

HumanOptics AG (www.humanoptics.com) develops, produces, and markets innovative implants for optical surgery, in particular intraocular lenses, which are artificial lenses implanted in the human eye. The areas of application include eye diseases such as cataracts, an affliction common around the world. Intraocular implants are also used in refractive surgery to correct refractive errors in the eye that can lead to poor vision. Their product range includes an artificial iris, which can be used to treat iris defects. The company also offers its target group, surgical eye doctors, supplies and complementary products as well as comprehensive consulting services. Shares of HumanOptics AG are listed on the Basic Board of the Frankfurt Stock Exchange as ISIN DE000A1MMCR6.

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