Laser device for eye surgery

An ophthalmology firm developed a new type of device for treating eyes with a femtosecond laser. Zühlke realised the system, particularly the electronics, mechanics and software according to international regulations.

Task
The customer develops and manufactures diagnostic and surgical devices for ophthalmology. In eye laser treatments, a curved flap is cut in the top layer of the cornea and pulled back. This flap was previously cut with an oscillating knife. The company wanted to use a femtosecond laser for this task. In the treatment, the ophthalmologist fixes the eye in place with a flexible handpiece using a vacuum. The base device deflects the laser beam through a swivelling arm into the handpiece and focuses it there. An ultra-precise X-Y deflection creates the cutting geometry. Zühlke’s task was to develop the device and design the system.

Implementation
As a first step in the project, Zühlke examined the technical feasibility of the undertaking. In order to verify the major risks early on, ideas and concepts were elaborated upon and implemented with the customer and other partners in a functional model with the handpiece and articulated arm. Initial cutting trials yielded very positive results. The findings were incorporated directly into the design specifications. Within a year, the mechanics, electronics and software were ready for the first prototype. The FDA had assigned the device software to the highest security class, so an independent security system was required. It was implemented in the electronics with a digital signal processor (DSP). The prototype was then tested for the first time in clinical trials on patients. The objectives of achieving thinner cuts of greater precision and shortening the surgical time were both met. After further optimisations, the device became a series product. The entire advance was developed in accordance with the customer’s development process.

Customer benefits
- The customer obtained important parts of the overall system from a single source thanks to Zühlke’s interdisciplinary expertise.
- Drawing on its experience in developing medical products, Zühlke helped to ensure prompt implementation of the regulatory requirements for the entire system.
- This risk-driven approach determined the major uncertainties in an early project phase using a functional model.