

R&D Tax Credits Case Studies: Medical Devices

The following are two medical device company case studies which further illustrate the types of projects and activities that will potentially qualify for the R&D tax credit. The eligibility of specific activities and expenditures will depend upon a closer examination of the facts and circumstances in relation to applicable guidance.

New Product Development

Company developed a new medical device with unique advanced features to improve the effectiveness and safety of hysteroscopic examinations as well as for use in surgical procedures utilizing continuous fluid flow endoscopes. Incorporating a unique and patented pressure regulating loop in the fluid supply side, the newly developed pump dramatically reduces instantaneous pressure variances during procedures and facilitates real-time monitoring of the rate of potentially harmful fluid loss.

Significant uncertainty was encountered in the development of the device related to the accuracy of the pressure maintained at the surgical cavity, the accuracy of the input and output fluid measurements, being able to maintain the required flow rate, and maintaining the set pressure during morcellation. This uncertainty led to numerous design iterations. The project involved electrical and mechanical engineering as well as software development. Experimentation to eliminate uncertainty including performance and safety testing was present in each phase of the product development. After extensive analysis of the expenditures and activities involved in this project, it was determined to qualify for purposes of the R&D tax credit.

Incremental Product Improvement

Company developed a new generation of medical device electronics for arthroscopic surgery application. This project involved the development of a totally new and different motor using new electronics and interacting with a much more advanced LCD touch screen. Prior models used push buttons and character displays. The development involved significant software and hardware modifications to an existing system that led to a vastly better, higher quality product. The improved product had new functionality, incorporating several new attachments allowing the device to be used for a greater number of procedures, which would not have been possible using the prior system's technology. The improved device is also far safer in that it incorporates a substantially improved human interface touch screen which greatly reduces the likelihood of surgeon error.

There were numerous and significant design iterations, performance and safety testing, as well as validation experiments to eliminate uncertainty in each phase of the product innovation. After extensive analysis of the expenditures and activities involved in this project, it was determined to qualify for purposes of the R&D tax credit.



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