

Pursuant to 21 CFR 807.92 the following summary is submitted.

1. Submitter's name-

Carl Zeiss, Inc.
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December 19, 1996

2. SMN System with STN system and permit individual sale of STN
Surgical Microscope/ Image Guided System and Instrument Based Image Guided System

3. We are claiming an exemption as a Surgical Microscope due to the exemption set forth in the Federal Register Notice dated December 7, 1994 which exempted surgical microscopes. Or in the alternative we are also claiming substantial equivalence to our MKM system which is used in a similar manner as our SMN system. Finally, we are claiming substantial equivalence to the Stealth Station sold by Sofamor Danek which is very similar to our STN system.

4. The Surgical Microscope Navigator (SMN) and the Surgical Tool Navigator (STN) System are a modular product group intended to provide the surgeon with navigational support during surgery. They permit the surgical team to load radiological imaging studies onto a workstation equipped with image processing and visualization software. After correlation of the patient position with the images, (the registration procedure) the system displays the position, trajectory and other localization information of the current "tool" interactively throughout the surgical procedure.

The SMN's primary "tool" is a surgical microscope that, through features such as an autofocus and heads-up display, permit the high accuracy localization of the critical focus and hence an area of interest in the patients anatomy. The STN by contrast uses a variety of "Pointers" and instruments as tools. Here the surgeon touches the area of interest with the pointer or instrument instead of virtually probing it with the microscope autofocus. The functionality of the SMN can be added to the STN as an upgrade and conversely the microscope functionality (i.e. SMN) can be added to an STN. Furthermore a system having both "modules" can easily be used in either configuration in a given surgical procedure.

Both systems localize the tools in space, to a high degree of accuracy, via an industry standard infra-red LED based camera system. The LED's coordinates are then transferred to the workstation which in turn converts them to the coordinate system of the imaging data and interactively displays them.

5. These devices will be used in the same manner as all Surgical Microscope/ Image Guided Systems are used and as all Instrument Based Image Guided Systems are used. These devices are used to aid the surgeon in visualizing the surgical site and guiding the surgeon through the surgical course. The systems do not take the place of the surgeon they are only a tool used to assist the surgeon during the procedure. Decisions about what to do and how to perform a procedure still rest firmly with the surgeon. These systems incorporate the original intended uses of our MKM system and now the STN system can be used as a stand alone navigational tool.

6. The SMN is substantially equivalent to our MKM system (Multiple Coordinate Manipulator) which is already cleared. Both of these systems are used in surgical procedures where magnification and illumination of the site is required. They are both ideally suited for stereotactically guided surgical procedures in any location of the body. Both systems utilize either identical or very similar microscopes. They both operate on the same stereotactic surgical planning system, which has been specially adapted for use with these systems and can be used to plan stereotactic-guided procedures.

The primary differences between the variations of the SMN and the MKM are that the MKM is capable of moving and tracking its position with internal servo-motors. While all versions of the SMN are passive and require manual positioning of the microscope, relying on an external light based localization system.

The STN system is virtually identical to the medical device known as the StealthStation® sold by Sofamor Danek. The primary difference is in the image processing software that runs on the workstation. Otherwise the localization system of both instruments are manufactured and supplied by the same company.