



MEDICAL TECHNOLOGIES LTD

K96/307

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510(k) Summary of Safety and Effectiveness

Submitter Information

Submitter: CMT Medical Technologies Ltd.
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Israel

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Summary Date: April 21, 1996

Name of Device and Classification

Proprietary Name: SMARTSPOT

Common Name: High Resolution Digital Imaging System

Classification: Accessory to 21 CFR 892.1650, Class II

Predicate Device

Manufacturer: S & S Inficon Inc.

Predicate Name: FC 2000

510(k) number: K911454

Description of the Device

The SMARTSPOT is a high resolution digital system for Digital Spot Imaging in Radiography/Fluoroscopy (R/F) X-ray rooms. It is designed to reduce (and even replace) the use of cassette filming and 105 mm spot cameras, and in this way reduce overall patient radiation exposure and examination time.

The system is based on a computer workstation running Windows NT as the operating system. The other main components are: a high resolution CCD camera, an advanced video processor, operation room and control room monitors, X-ray and TV interfaces, Hardcopy Laser Camera interface and a 2 GBytes internal hard disk.

Intended Use

The SMARTSPOT enhances the quality of the fluoroscopy image, enables acquisition and display of high resolution (1024 x 1024 pixels) radiographic images and gives the user the possibility to perform advanced studies involving image digital subtraction, such as Roadmapping and DSA, that were not possible with conventional techniques.

Fields of application of the system are: gastrointestinal examinations, interventional procedures, peripheral angiography studies, urology examinations and other routine fluoroscopy studies.

Comparison to the Predicate

Both systems have the same intended use. They have almost identical features, same spatial resolution and same digitization depth.

Both systems are computer controlled devices, although different platforms and different operating systems but both in the mainstream of today's computer technology.

The main and almost only relevant difference is the TV camera used: the SMARTSPOT integrates a digital CCD camera vs. the Pick-up tube type used by the predicate device. CCD cameras are already widely used in fluoroscopic digital devices. These cameras show a comparable spatial resolution and dynamic range as the pick-up tube counterparts but they outperform them in terms of cost-effectiveness and long term stability.

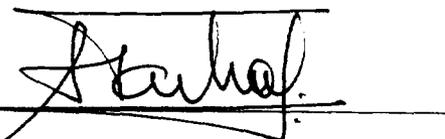
Safety information

The device is designed to comply at least with the minimum response requirements stated in the initial Hazard Analysis included in this notification, and with voluntary international standard IEC 601-1 for medical electrical equipment regarding both its safety (part 1) and electromagnetic compatibility (part 2) requirements.

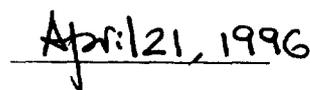
After completion of the pre-production series, the device will be submitted for compliance tests with the above mentioned requirements in a certified laboratory. Prior to commercial distribution, the system will be β tested to meet specifications including safety requirements.

Conclusion

We conclude that, once finished the development and testing phase as described, the SMARTSPOT will be as safe and effective as the predicate device.



Imre Farkash
Quality Assurance Manager



date