

**510(k) Summary PER 21 CFR 807.92****1: Submitted by:**

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JAN -2 1997

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Summary prepared: 19. June 1996

**2: Device Name:**

Intra Vascular Ultrasound System (IVUS) option for Vingmed Sound Color Flow Mapping System

**3: Predicate Device:**

CVIS Insight III, K921750

**4: Device Description:**

The IVUS consists of a basic scanner unit integrated into the CFM 775/800 ultrasound system. The basic scanner unit consists of a card rack mounted into the CFM 775/800; a video switch board mounted into the CFM 775/800 card rack; cables for interconnections; a connector for the motor drive and components that are common with the CFM 775/800. These common components include the keyboard and display, connectors for ECG and AUX, power supply, and internal computer (EchoPac) for video grabbing and archival (CFM 800 only), and peripherals such as a VCR printer. The system is used with specified off-the-shelf motor pod and ultrasound catheters not manufactured by Vingmed Sound A/S.

**5: Intended Use:**

The IVUS option for the CFM product family is intended for intravascular applications at all system control settings. When used with a Vingmed Color Flow Mapping (CFM) imaging system the device can be used to obtain, store and retrieve 2D images and perform measurements and analysis on these.

The IVUS option is intended for use by duly licensed physician who has received appropriate training in proper operation of the device.

As with any procedure of this sort, the physician conducting the examination must exercise sound medical judgment in the selection of patients for this product, and be skilled in interpreting the echocardiographic data obtained from intra-vascular ultrasound devices.

The IVUS option is intended to be used with a Vingmed Color Flow Mapping (CFM) imaging system to apply ultrasound energy from an intra-vascular catheter to:

- Produce 2D images that can be used to detect abnormalities.
- Store images in the CFM system or via the CFM system to other storage media.

Images can be retrieved from the CFM system or storage media for measurement and analysis.

**6: Comparison With Predicate Device**

The following table depicts the similarities and differences between the Vingmed Sound IVUS System and the CVIS Insight III.

**Table 1: General system comparison table**

	<b>New device</b>	<b>Predicate device</b>
	IVUS	CVIS Insight III
510(k) number		K921750
Indications for use	Intra cardiac	Intra cardiac
	Coronary vessel	Coronary vessel
	Peripheral vessel	Peripheral vessel
General device description	Embedded processor for system control	Embedded processor for system control
	Operator interface with imaging controls, alphanumeric keyboard, trackball, TGC controls, software menu controls	Operator interface with alphanumeric keyboard, remote control, trackball, software menu controls
	B&W - or colour monitor	B&W monitor
	Picture-in-picture (angio and ultrasound on one screen)	Picture-in-picture (angio and ultrasound on one screen)
	Two traces	Two traces
Imaging modes	B-mode	B-mode
	360 degree image format	360 degree image format
Catheters	Single element rotating transducer	Single element rotating transducer
	Single element fixed transducer with rotating mirror	Single element fixed transducer with rotating mirror
Measurements	General (distance, area and % stenosis)	General (distance, area and % stenosis)
Acoustic output and device settings used	Track 1	Track 1
Image archiving and communications	EchoPAC, magneto-optical disc, video	Video, digital raw-data transfer, research option (RF output)
General safety and effectiveness	Conforms to IEC601-1, EN60601-1-2	-

**7: Nonclinical tests:**

The product has been designed for electrical patient safety by complying with IEC 601-1 and EN 60601-1-2, EN 55011 and IEC 801-2/-3/-4/-5 for EMC protections. Other tests performed have included measurements of acoustic output in accordance with the FDA

guidance document of December 1985 for measuring and reporting acoustic output of diagnostic ultrasound medical devices. The software is developed in accordance with a software development plan and the software level of concern, as described in the document "Reviewers Guidance for Computer Controlled Medical Devices Undergoing 510(k) review" dated August 29,1991, is moderate.

**8: Conclusion:**

Based on the analysis of the comparison matrix described in 6 above and the results of the nonclinical testing described in 7 above, Vingmed Sound A/S has concluded that the Intra Vascular Ultrasound System (IVUS) option for Vingmed Sound Color Flow Mapping System is safe, effective, ad performs as well as or better than the legally marketed device in 3 above.