SUMMARY OF SAFETY AND EFFECTIVENESS
MATERIALISE CT-MODELLER SYSTEM

K970617

APR 21 1997

I. GENERAL INFORMATION

Classification Name:	System, Image Processing
Common Name:	Image Processing System
Device Trade Name:	Materialise CT-Modeller System
Classification Code:	90LLZ
Submitter's Name & Address:	Materialise N.V. Kapeldreef 60 B-3001 Leuven Belgium
Establishment Registration No:	Applied for
Contact Person:	Wilfried Vancraen
Summary Preparation Date:	February 14, 1997

II. PREDICATE DEVICE

The **CT-Modeller System** is claimed to be substantially equivalent in material, design, and function to the SurgiCAD View System cleared by FDA under 510(k) K924630 on April 7, 1993.

III. Device Description

The Materialise **CT-Modeller System** is intended for use as a software interface and image segmentation system for the transfer of imaging information from a medical scanner such as a Magnetic Resonance imaging scanner or CT scanner. The input data file is processed by the **CT-Modeller System** and the result is an output data file which may then be used as input data for a CAD or Rapid Prototyping System.

IV. STERILIZATION

The **CT-Modeller System** is provided non-sterile.

V. INDICATIONS FOR USE

The Materialise **CT-Modeller System** is intended for use as a software interface and image segmentation system for the transfer of imaging information from a medical scanner such as a Magnetic Resonance imaging scanner or CT scanner. The input data file is processed by the **CT-Modeller System** and the result is an output data file which may then be used as input data for a CAD or Rapid Prototyping System. The **CT-Modeller System** which is the subject of this 510(k) premarket notification is confined solely to the software image segmentation system.

VI. SUBSTANTIAL EQUIVALENCE

The **CT-Modeller System** is considered to be substantially equivalent to the SurgiCAD View System.

VII. CONCLUSION

The **CT-Modeller System** is considered to be substantially equivalent in design, material and function to the SurgiCAD View System and is believed to perform as well as the SurgiCAD System.