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SEP - 9 1996

510K SUMMARY

FOR

DEVICE TRADE NAME: **CE-3000 CONTRAST ENHANCER**

COMMON NAME: **VIDEO CONTRAST ENHANCER**

CLASSIFICATION NAME: **ENDOSCOPE AND ACCESSORIES** (876.1500)

SUBMITTED BY: **CHARLES A. BRASS - ADMINISTRATOR, QA/QC**

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CLAIMING SUBSTANTIAL EQUIVALENCE TO:

DIGIVISION - FLUOROVISION

COMMON NAME: **VIDEO CONTRAST ENHANCER**

CLASSIFICATION NAME: **IMAGE-INTENSIFIED FLUOROSCOPIC X-RAY SYSTEM (ACCESSORY)** (PER 21 CFR 892.1650)

510K NUMBER K864584

PREPARED June 7, 1996

DATE

510K SUMMARY

Description

The CE-3000 takes a video signal in and allows an operator to control, via three knobs on the front panel, the local gain of spatial frequencies, through high speed signal processing, to generate video optimized for specific functions in real time. The three knobs on the front of the device, DETAIL (kernel size), CONTRAST and BACKGROUND, allow the operator to "dial-in" the picture to his preference or he may press the PRESET button to set the enhancement to predetermined factory settings. A SPLIT screen button is available to help the user to set the optimum enhancement. Selecting the BYPASS switch displays original unprocessed video.

The CE-3000 has a main processor circuit board (core board) which incorporates DigiVision, Inc.'s patented V-Lace technology (for video locally adaptive contrast enhancement) can be adjusted to give the appropriate enhancement to any video scene. The image processing algorithm is expressed as:

$$Y = c(\mathbf{X}-\bar{\mathbf{X}}(d)) + (1-b)\bar{\mathbf{X}}(d) + b\mathbf{M}.$$

The CE-3000 incorporates software as embedded software in the micro controller which is used, in turn to program an EEPROM. There exists no user changeable software.

The enclosure for the CE-3000 is metal (aluminum). The other components are commercially available hardware and electronic components and printed circuit cards manufactured to DigiVision, Inc. specifications.

Intended use

The CE-3000 Contrast Enhancer like the FluoroVision, may be used in any application where a viewing device (fluoroscope, endoscope, laparoscope, etc.) and monitor is incorporated to aid in diagnosis and treatment of a disease such as an arthroscopy or cholecystectomy. Despite the different indication statements, both devices have the same function and purpose and the differences in intended use does not create new safety or effectiveness issues.

510K SUMMARY

Technological Characteristics

The technology of both the CE-3000 and the FluoroVision are similar. The CE-3000 takes advantage of advances in electronics technology (since the development of the FluoroVision) which allows the reduction of the size and quantity of components. All other components are comparable (i.e., Hospital power cord, Input/Output cords, metal case, etc.).

Performance

Since these two devices use the same algorithm, the output and performance is identical. We have included some pictures of examples of processing (see **Pictures of Processing).**

Safety and Effectiveness

DigiVision has no knowledge of any adverse safety or effectiveness issues nor do we expect such problems. The CE-3000 design and use precludes any output of information that could plausibly produce a decision-maker to cause an error. Should the CE-3000 fail in any way it may be removed from the system (i.e., connect the camera directly to the monitor).

The CE-3000 has been evaluated by Underwriters Laboratories and found to pass electrical safety tests to UL 544, IEC 601-1, and approved to bear the UL 544 Listing Mark, IEC 601 Classification Mark and the C-UL IEC 601 Classification Mark.

The CE-3000 is in compliance with the EMC requirements as defined in European Standard EN60601-1-2: 1993.

Classification

Although the cover sheet of this submission indicates that the classification sought is Endoscope and/or Accessories, we request clearance to market the device for similar applications where video image enhancement is desired classified elsewhere in the Code of Federal Regulations. The CE-3000 could be classified in the same way monitors or scopes (i.e., broncoscopes, esophagoscope, etc.) are, provided they accept RS-170, RS-170A or CCIR video.