

K962651

**Revised Summary for S-52**

**516(k)**  
**Summary (Revision 1)**

**SEP 30 1996**

Del Medical Systems feels the S-52 Electronic Video Laparoscope is substantially equivalent to the EVL-F marketed by Fujinon under K-902197/B and K912859/A in terms of technology and intended use. DMS also feels that the device is similar to the device marketed by Smith and Nephew in terms of technology, shape, size and composition and intended use.

The design of the S-52 is virtually identical to the Smith & Nephew device and comparative to the Fujinon device. Since the design is comparable, technology virtually identical, the specifications, apart from, the flexible vs rigid issue, which makes no difference when operated by a trained physician the devices are very similar, and the intended use the same. DMS feels that these minor differences have no impact on the safe use and/or effectiveness of the device.

The wide use of the same or very similar instruments has led to the safe use of the device in many practitioner's hands.

Confirmation of Substantial Equivalence Determination made by Del Medical Systems. The device is virtually identical to the devices in commercial distribution, such as the Fujinon filed under EVL-F- K902197/B and K912859/A, which the FDA has reviewed and sent Fujinon the appropriate paperwork, allowing for the marketing of this product. We also cite Smith & Nephew and Welch Allyn as makers/marketers of "distal end CCD devices" (Charged-coupled Device Laparoscopes) as other devices of comparison. Each of the predicate devices has the same intended use.

FDA/CDRH/ODE/DMC

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