

K920530

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J. SUMMARY OF SAFETY AND EFFECTIVENESS

MAR 21 1988

1. Name and Address

This Summary of Safety and Effectiveness is being submitted by Medco Instruments, Inc., 4500 W. 137th Street, Crestwood, IL 60445. The telephone number is 708-597-7400.

2. Name of the Device

The device is generally known as a Laceration Tray.

3. Identification of the Predicate Device

Medikmark's Laceration Tray, K920341.

4. Description of the Device

Medco's Laceration Tray is a convenient assemblage of common medical devices which are used by medical professionals during minor surgical procedures, including, but not limited to, wound closures, incisions and drainage and comparable minor procedures. The tray is sold sterile.

5. Intended Use of the Device

The Laceration Tray is an assemblage of surgical accessories, each of which is intended to be used in accordance with generally accepted minor surgical procedures.

6. Comparison of Technological Characteristics

The differences between Medco's Laceration Tray and Medikmark's Laceration Tray are minor and do not impact the safety and effectiveness of the device in any significant way.

7. Safety

Medco reviewed the MDR records filed with CDRH relating to laceration trays. A manual search was conducted in the Product SOS™² book; no MDRs were reported for laceration trays. There are 3 surgical instrument trays that malfunctioned; one is a tubing organizer and two are sterilization container systems, all of which are very different from a laceration tray. An additional search was done in a CD ROM database³ for laceration trays. No MDRs were filed for laceration trays. We then searched for the product code, LRO which resulted in 2 MDRs. One is a skin scrub tray and the other is a spray kit. Finally, we searched for surgical procedure packs/kits and one report indicated that a cannula malfunctioned in the kit resulting in chamber collapse. All of these reports are attached.

² Product SOS™, Medical Economics Data Production Company, Montvale, NJ 07645-1742.

³ The Medical Device Library, IHS Regulatory Products, 15 Inverness Way East, Englewood, CO 80150.