§ 876.5955 Peritoneo-venous shunt.

(a) Identification. A peritoneo-venous shunt is an implanted device that consists of a catheter and a pressure actuated one-way valve. The catheter is implanted with one end in the peritoneal cavity and the other in a large vein. This device enables ascitic fluid in the peritoneal cavity to flow into the venous system for the treatment of intractable ascites.

(b) Classification. Class II. The special controls for this device are FDA's:

2. “510(k) Sterility Review Guidance of 2/12/90 (K90–1),” and
3. Backflow specification and testing to prevent reflux of blood into the shunt.

§ 876.5970 Hernia support.

(a) Identification. A hernia support is a device, usually made of elastic, canvas, leather, or metal, that is intended to be placed over a hernial opening (a weakness in the abdominal wall) to prevent protrusion of the abdominal contents. This generic type of device includes the umbilical truss.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of this part subject to the limitations in §876.9. The device is also exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of §820.180, regarding general requirements concerning records, and §820.198, regarding complaint files.

§ 876.5990 Extracorporeal shock wave lithotripter.

(a) Identification. An extracorporeal shock wave lithotripter is a device that focuses ultrasonic shock waves into the body to noninvasively fragment urinary calculi within the kidney or ureter. The primary components of the device are a shock wave generator, high voltage generator, control console, imaging/localization system, and patient table. Prior to treatment, the urinary stone is targeted using either an integral or stand-alone localization imaging system. Shock waves are typically