§ 807.97 Misbranding by reference to premarket notification.

Submission of a premarket notification in accordance with this subpart, and a subsequent determination by the Commissioner that the device intended for introduction into commercial distribution is substantially equivalent to a device in commercial distribution before May 28, 1976, or is substantially equivalent to a device introduced into commercial distribution after May 28, 1976, that has subsequently been reclassified into class I or II, does not in any way denote official approval of the device. Any representation that creates an impression of official approval of a device because of complying with the premarket notification regulations is misleading and constitutes misbranding.

§ 807.100 FDA action on a premarket notification.

(a) After review of a premarket notification, FDA will:

1. Issue an order declaring the device to be substantially equivalent to a legally marketed predicate device;
2. Issue an order declaring the device to be not substantially equivalent to any legally marketed predicate device;
3. Request additional information; or
4. Withhold the decision until a certification or disclosure statement is submitted to FDA under part 54 of this chapter.

(b) FDA will determine that a device is substantially equivalent to a predicate device using the following criteria:

1. The device has the same intended use as the predicate device; and
2. The device:
   (i) Has the same technological characteristics as the predicate device; or
   (ii)(A) Has different technological characteristics, such as a significant change in the materials, design, energy source, or other features of the device from those of the predicate device; and
   (B) The data submitted establishes that the device is substantially equivalent to the predicate device and contains information, including clinical data if deemed necessary by the Commissioner, that demonstrates that the device is as safe and as effective as a legally marketed device; and
3. The predicate device has not been removed from the market at the initiative of the Commissioner of Food and Drugs or has not been determined to be misbranded or adulterated by a judicial order.