# CPG Sec. 300.600 Commercial Distribution with Regard to Premarket Notification (Section 510(k))

BACKGROUND:

Many questions have been raised concerning what constitutes commercial distribution. This Compliance Policy Guide is based on a March 24, 1978, response to a formal request for an Advisory Opinion on this subject (Docket Number 77A-0307).

POLICY:

If a manufacturer can meet all of the following conditions, we consider a device to presently be in commercial distribution and also to have been in commercial distribution before May 28, 1976, even though no units of the device had been delivered to purchasers or consignees before that date:

1. The device was displayed, advertised, or otherwise offered for sale before May 28, 1976, for a specific intended purpose or purposes, with no limitations (e.g., no limitation to research or investigational use);
2. The manufacturer had, before May 28, 1976, accepted, or been prepared to accept, at least one order to purchase the device that resulted, or would have resulted, in a contract of sale for the device in the United States, generally with delivery to occur immediately or at a promised future date;
3. The device was not being offered or accepted only for research or investigational use; *and*
4. The manufacturer of the device can provide adequate documentation establishing (1) through (3) above to the satisfaction of the Food and Drug Administration.

This opinion affects device firms' promotional activities during the pendency of 510(k)'s (premarket notification submission). Although a firm may advertise or display a device that is the subject of a pending 510(k) -- in the hope that FDA will conclude that the device is substantially equivalent to a pre-amendments device -- a firm may not take orders, or be prepared to take orders, that might result in contracts of sale for the device unless limited to research or investigational use.

*Material between asterisks is new or revised*

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