The following notification is being circulated in accordance with Article 10.4.

1. **Party and Agency:** United States: Food and Drug Administration (78)

2. **Provision of the Agreement:** Proposed technical regulation (Article 2.5.2)

3. **Product(s) covered, CCCN Heading (National Tariff Heading where applicable):**
   - Medical devices

4. **Title of project:** Premarket approval of medical devices.

5. **Description:** The Food and Drug Administration (FDA) proposes procedures for the premarket approval (pma) of medical devices. The proposal prescribes the contents of an application for pma and sets forth criteria FDA will employ in approving, disapproving, or withdrawing approval of a pma.

6. **Objective and rationale:** To provide reasonable assurance of medical devices safety and effectiveness before introduction to the market.


8. **Where published, when adopted:** Federal Register

9. **Final date for submission of comments:** 13 April 1981

10. **Proposed date of adoption and entry into force:** To be determined.