# HR 5651

Medical Device User Fee and Modernization Act of 2002

**Congress:** 107 (2001–2003, Ended)
**Chamber:** House
**Policy Area:** Health
**Introduced:** Oct 16, 2002
**Current Status:** Became Public Law No: 107-250.
**Latest Action:** Became Public Law No: 107-250. (Oct 26, 2002)
**Law:** 107-250 (Enacted Oct 26, 2002)
**Official Text:** https://www.congress.gov/bill/107th-congress/house-bill/5651

## Sponsor

**Name:** Rep. Greenwood, James C. [R-PA-8]
**Party:** Republican • **State:** PA • **Chamber:** House

## Cosponsors (1 total)

| Cosponsor | Party / State | Role | Date Joined |
|---|---|---|---|
| Rep. Eshoo, Anna G. [D-CA-14] | D · CA | | Oct 16, 2002 |

## Committee Activity

| Committee | Chamber | Activity | Date |
|---|---|---|---|
| Energy and Commerce Committee | House | Discharged From | Oct 17, 2002 |

## Subjects & Policy Tags

**Policy Area:**

Health

## Related Bills

| Bill | Relationship | Last Action |
|---|---|---|
| 107 HR 3580 | Related bill | **Oct 15, 2002:** Supplemental report filed by the Committee on Energy and Commerce, H. Rept. 107-728, Part II. |

## Summary (as of Oct 16, 2002)

Amends the Federal Food, Drug, and Cosmetic Act to establish a new program that subjects, beginning on October 1, 2002, each medical device manufacturer to a medical device fee for certain applications, reports, application supplements, and submissions sent to the Food and Drug Administration for evaluation. Grants exceptions.

Restricts the medical device user fees collected to being used to defray increases in the costs of the resources allocated for the review of device applications. Exempts certain entities submitting premarket reports from being subject to a fee.

Directs the Secretary to accredit persons who are not Federal employees to conduct the inspections required under the Act for establishments that manufacture, prepare, propagate, compound, or process class II or class III devices.

Considers it a violation of the Act for an accredited inspector to: (1) breach the standards of accreditation of this section; (2) pose a threat to public health; or (3) fail to act in accordance with this section.

Requires the Secretary to establish within the Office of the Commissioner of Food and Drugs an Office to perform various functions, including to ensure the timely premarket review of combination products.

Directs the Secretary to provide guidance on ensuring safety of pediatric devices and providing protections for pediatric subjects in clinical investigations into the safety and effectiveness of such devices.

Requires reprocessed single-use devices to carry prominently on the label a statement identifying the product as such, along with the name of the person responsible for reprocessing and the manufacturer.

## Actions Timeline

- **Oct 26, 2002:** Signed by President.
- **Oct 26, 2002:** Signed by President.
- **Oct 26, 2002:** Became Public Law No: 107-250.
- **Oct 26, 2002:** Became Public Law No: 107-250.
- **Oct 25, 2002:** Presented to President.
- **Oct 25, 2002:** Presented to President.
- **Oct 18, 2002:** Message on Senate action sent to the House.
- **Oct 17, 2002:** Passed/agreed to in Senate: Passed Senate without amendment by Unanimous Consent.(consideration: CR S10752-10754)
- **Oct 17, 2002:** Passed Senate without amendment by Unanimous Consent. (consideration: CR S10752-10754)
- **Oct 16, 2002:** Introduced in House
- **Oct 16, 2002:** Introduced in House
- **Oct 16, 2002:** Referred to the House Committee on Energy and Commerce.
- **Oct 16, 2002:** Mr. Armey asked unanimous consent to discharge from committee and consider.
- **Oct 16, 2002:** Committee on Energy and Commerce discharged.(consideration: CR H7964-8009)
- **Oct 16, 2002:** Committee on Energy and Commerce discharged. (consideration: CR H7964-8009)
- **Oct 16, 2002:** Passed/agreed to in House: On passage Passed without objection.(text: CR H7965-7974)
- **Oct 16, 2002:** On passage Passed without objection. (text: CR H7965-7974)
- **Oct 16, 2002:** Considered by unanimous consent.
- **Oct 16, 2002:** Motion to reconsider laid on the table Agreed to without objection.
- **Oct 16, 2002:** Received in the Senate, read twice.