

# H.R.3580

## Food and Drug Administration Amendments Act of 2007 (Engrossed as Agreed to or Passed by House)

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### SEC. 226. UNIQUE DEVICE IDENTIFICATION SYSTEM.

- (a) In General- Section 519 (21 U.S.C. 360i) is amended--
- (1) by redesignating subsection (f) as subsection (g); and
  - (2) by inserting after subsection (e) the following:

#### Unique Device Identification System

(f) The Secretary shall promulgate regulations establishing a unique device identification system for medical devices requiring the label of devices to bear a unique identifier, unless the Secretary requires an alternative placement or provides an exception for a particular device or type of device. The unique identifier shall adequately identify the device through distribution and use, and may include information on the lot or serial number.'

- (b) Conforming Amendment- Section 303 (21 U.S.C. 333) is amended--
- (1) by redesignating the subsection that follows subsection (e) as subsection (f); and
  - (2) in paragraph (1)(B)(ii) of subsection (f), as so redesignated, by striking '519(f)' and inserting '519(g)'.