

Public Law 109–96  
109th Congress

An Act

To amend the Federal Food, Drug, and Cosmetic Act to provide for the regulation of all contact lenses as medical devices, and for other purposes.

Nov. 9, 2005  
[S. 172]

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,*

**SECTION 1. REGULATION OF CERTAIN ARTICLES AS MEDICAL DEVICES.**

Section 520 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j) is amended by adding at the end the following subsection:

“Regulation of Contact Lens as Devices

“(n)(1) All contact lenses shall be deemed to be devices under section 201(h).

“(2) Paragraph (1) shall not be construed as bearing on or being relevant to the question of whether any product other than a contact lens is a device as defined by section 201(h) or a drug as defined by section 201(g).”

Approved November 9, 2005.

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LEGISLATIVE HISTORY—S. 172:

SENATE REPORTS: No. 109–110 (Comm. on Health, Education, Labor, and Pensions).

CONGRESSIONAL RECORD, Vol. 151 (2005):  
July 29, considered and passed Senate.  
Oct. 26, considered and passed House.

