

108TH CONGRESS
1ST SESSION

H. R. 2218

IN THE SENATE OF THE UNITED STATES

NOVEMBER 20, 2003

Received

DECEMBER 9, 2003

Read twice and referred to the Committee on Health, Education, Labor, and
Pensions

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.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

1 **SECTION 1. FINDINGS.**

2 The Congress finds as follows:

3 (1) All contact lenses have significant effects on
4 the eye and pose serious potential health risks if im-
5 properly manufactured or used without appropriate
6 involvement of a qualified eye care professional.

7 (2) Most contact lenses currently marketed in
8 the United States, including certain plano and deco-
9 rative contact lenses, have been approved as medical
10 devices pursuant to premarket approval applications
11 or cleared pursuant to premarket notifications by
12 the Food and Drug Administration (“FDA”).

13 (3) FDA has asserted medical device jurisdic-
14 tion over most corrective and noncorrective contact
15 lenses as medical devices currently marketed in the
16 United States, including certain plano and decora-
17 tive contact lenses, so as to require approval pursu-
18 ant to premarket approval applications or clearance
19 pursuant to premarket notifications.

20 (4) All contact lenses can present risks if used
21 without the supervision of a qualified eye care pro-
22 fessional. Eye injuries in children and other con-
23 sumers have been reported for contact lenses that
24 are regulated by FDA as medical devices primarily
25 when used without professional involvement, and
26 noncorrective contact lenses sold without approval or

1 clearance as medical devices have caused eye injuries
2 in children.

3 **SEC. 2. REGULATION OF CERTAIN ARTICLES AS MEDICAL
4 DEVICES.**

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

8 "Regulation of Contact Lens as Devices
9 "(n)(1) All contact lenses shall be deemed to be de-
10 vices under section 201(h).

11 "(2) Paragraph 1 shall not be construed as having
12 any legal effect on any article that is not described in that
13 paragraph.".

Passed the House of Representatives November 19,
2003.

Attest: JEFF TRANDAHL,
Clerk.