

103^D CONGRESS
2^D SESSION

H. R. 5188

To authorize the export of medical devices to countries which have approved such devices.

IN THE HOUSE OF REPRESENTATIVES

OCTOBER 5, 1994

Mr. KIM introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To authorize the export of medical devices to countries which have approved such devices.

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

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Medical Device Export
5 Promotion Act of 1994”.

6 **SEC. 2. DEVICE EXPORTS.**

7 In the administration of section 801 of the Federal
8 Food, Drug, and Cosmetic Act, the Secretary of Health
9 and Human Services shall permit the export of a medical
10 device which—

1 (1) is intended for export to a country which as
2 determined by the Secretary has a medical device
3 approval process which provides reasonable assur-
4 ance of the safety and effectiveness of medical de-
5 vices,

6 (2) has been approved under the laws of the
7 country to which it is intended for export,

8 (3) is labeled on the outside of the shipping
9 package that it is intended for export, and

10 (4) is not sold or offered for sale in domestic
11 commerce.

12 A medical device which is exported under the authority
13 of this Act may not thereafter be imported into the United
14 States unless its importation has been approved by the
15 Secretary of Health and Human Services.

16 **SEC. 3. REVIEW.**

17 The Secretary of Health and Human Services shall
18 conduct an annual review of the medical device approval
19 laws of countries not described in section 2(1) to deter-
20 mine if such laws provide reasonable assurance of the safe-
21 ty and effectiveness of medical devices.

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