

104TH CONGRESS
1ST SESSION

H. R. 485

To expand the authority for the export of devices.

IN THE HOUSE OF REPRESENTATIVES

JANUARY 11, 1995

Mr. KIM (for himself, Mr. MOORHEAD, Mr. ROYCE, and Mrs. SEASTRAND) introduced the following bill; which was referred to the Committee on Commerce and, in addition, to the Committee on International Relations, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To expand the authority for the export of 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. AUTHORITY.**

4 (a) IN GENERAL.—In the administration of section
5 801(e)(2) of the Federal Food, Drug, and Cosmetic Act
6 (21 U.S.C. 381(e)(2)), on the basis of either of the follow-
7 ing notices with respect to a medical device the Secretary
8 of Health and Human Services shall make the determina-
9 tion in that section that the exportation of such medical
10 device is not contrary to public health and safety and has

1 the approval of the country to which it is intended for ex-
2 port:

3 (1) Notice by the exporting company of ap-
4 proval for marketing or for investigational use of the
5 medical device in the European Community (such
6 approval for marketing referred to as the “CE”
7 mark).

8 (2) Notice by the exporting company of ap-
9 proval for marketing or investigational use of the
10 medical device by the Ministry of Health and Wel-
11 fare of Japan or by another appropriate body in the
12 government of Japan.

13 In the case of a medical device approved only for investiga-
14 tional use, this subsection shall not apply unless the initial
15 destination country has also specifically approved such
16 medical device for investigational use.

17 (b) APPLICATION.—Subsection (a) does not apply to
18 any medical device which has been banned by the Sec-
19 retary of Health and Human Services under section 516
20 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
21 360f).

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