

104TH CONGRESS
1ST SESSION

S. 572

To expand the authority for the export of devices, and for other purposes.

IN THE SENATE OF THE UNITED STATES

MARCH 16, 1995

Mr. COATS introduced the following bill; which was read twice and referred to the Committee on Labor and Human Resources

A BILL

To expand the authority for the export of 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,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Medical Device Expor-
5 tation Act of 1995”.

6 **SEC. 2 AUTHORITY.**

7 (a) EXPORTATION OF DEVICES.—

8 (1) IN GENERAL.—In the administration of sec-
9 tion 801(e)(2) of the Federal Food, Drug, and Cos-
10 metic Act (21 U.S.C. 381(e)(2)), the Secretary of
11 Health and Human Services shall make the deter-

1 mination under such section, on the basis of a notice
2 described in paragraph (2) with respect to a medical
3 device, that the exportation of the device is not con-
4 trary to public health and safety and has the ap-
5 proval of the country to which the device is intended
6 for export.

7 (2) NOTICE REQUIREMENT.—A determination
8 made under paragraph (1) shall be based on either
9 of the following notices:

10 (A) Notice to the Secretary by the export-
11 ing company of approval for marketing or in-
12 vestigational use of the device in the European
13 Community (such approval for marketing re-
14 ferred to as the “CE” mark).

15 (B) Notice to the Secretary by the export-
16 ing company of approval for marketing or in-
17 vestigational use of the device by the Ministry
18 of Health and Welfare of Japan or by another
19 appropriate body in the government of Japan.

20 (b) APPLICABILITY.—

21 (1) INVESTIGATIONAL USE.—In a case of a de-
22 vice approved only for investigational use, subsection
23 (a) shall not apply unless the initial country of des-
24 tination has also approved the device for investiga-
25 tional use.

1 (2) BANNED DEVICE.—Subsection (a) shall not
2 apply to any device that has been banned by the
3 Secretary of Health and Human Services under sec-
4 tion 516 of the Federal Food, Drug, and Cosmetic
5 Act (21 U.S.C. 360f).

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