H. R.    

To amend the Federal Food, Drug, and Cosmetic Act to exempt from regulation as devices non-invasive diagnostic devices, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

Mr. Biggs introduced the following bill; which was referred to the Committee on ______________________

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to exempt from regulation as devices non-invasive diagnostic 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 Innovation Ac-
5 celeration Act of 2020”.

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May 18, 2020 (10:18 a.m.)
SEC. 2. EXEMPTING NON-INVASIVE DIAGNOSTIC DEVICES FROM REGULATION AS DEVICES.

Section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h)) is amended—

(1) in the second sentence by inserting before the period at the end the following: “or any non-invasive diagnostic device”; and

(2) by adding at the end the following: “For purposes of the preceding sentence, the term ‘non-invasive’ means, with respect to a diagnostic device, that the device does not penetrate the skin or any other membrane of the body, is not inserted or implanted into the body, causes no more than ephemeral compression or temperature changes to in situ bodily tissues, and does not subject bodily tissues to ionizing radiation.”.