

AMENDMENT TO COMMITTEE PRINT**OFFERED BY M __. _____****(MDUFA_020, June 20, 2007)**

Page 27, redesignate subsection (b) as subsection (c) and insert after line 15 the following:

1 (b) CONSIDERATION.—In determining the effective-
2 ness of the premarket notification and classification au-
3 thority under section 510(k) and 215(f) and (i), the study
4 under subsection (a) shall consider the Secretary’s evalua-
5 tion of the respective intended uses and technologies of
6 such devices, including the effectiveness of the Secretary’s
7 comparative assessment of technological characteristics
8 such as device materials, principles of operations, and
9 power sources.

Add at the end of title II, add the following new section (and conform the table of contents accordingly):

10 **SEC. __. UNIQUE DEVICE IDENTIFICATION SYSTEM.**

11 Section 519 of the Federal Food, Drug, and Cosmetic
12 Act (21 U.S.C. 360i) is amended—

13 (1) by redesignating subsection (f) as sub-
14 section (g); and

