This guidance was written prior to the February 27, 1997 implementation of FDA's Good Guidance Practices, GGP's. It does not create or confer rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both. This guidance will be updated in the next revision to include the standard elements of GGP's.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1390 Piccard Drive
Rockville, MD 20850

February 14, 1995

Dear Medical Device Manufacturer:

The Food and Drug Administration, Center for Devices and Radiological Health (CDRH), is writing this letter to address medical device issues related to Pentium™ processors designed and manufactured by Intel Corporation, Santa Clara, California. Intel Corporation recently acknowledged the existence of a flaw in some (approximately 6 million) Intel Pentium™ processors. CDRH is concerned that these flawed Pentium™ processors may have the potential to directly affect medical devices which:

- incorporate, as a component, a Pentium™ processor in the device design;
- incorporate, as a component, a personal computer utilizing a Pentium™ processor; or
- are software accessories to a medical device which can be used on a computer system incorporating a Pentium™ processor.

An Agency-wide policy on the use of flawed Pentium™ processors for manufacturing or process control systems and in the computation of data used for regulatory submissions is currently under development.

With certain inputs, Pentium™ processor floating point divide instructions will produce inaccurate results. Specific details are contained in an Intel Corporation report entitled *Statistical Analysis of Floating Point Flaw in the Pentium™ Processor (1994),* dated November 30, 1994.

Intel concluded that:

- for the majority of Pentium™ processor applications, the flaw will not affect operation;
- users in the scientific/engineering fields who require high-precision mathematical functions may need to replace their Pentium™ processor or modify the software they use.

Based on the Intel report, the possibility exists that the flawed Pentium™ processors could cause a medical device to produce erroneous quantitative results or otherwise perform outside of the specifications and thus may adversely affect the device's safety or effectiveness. The significance of the flawed Pentium™ processor for a particular medical device depends upon the specific application. The occurrence of safety or effectiveness problems in a Pentium™ processor based medical device or software accessory depends upon:

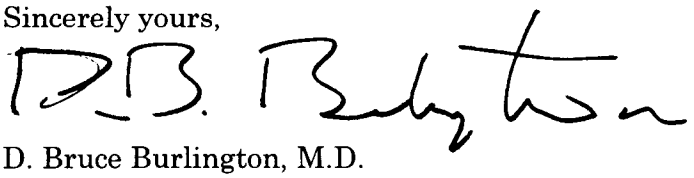
- the frequency with which specific floating point divide operations are used;
- the data input to the floating point hardware divide unit; and
- the manner in which the results of the floating point divide instructions are used in calculations or processor actions.

It is likely that for most medical device applications the reported flaw in the Pentium™ processor would have a negligible effect on device safety or effectiveness. However, under Good Manufacturing Practices (GMP) regulations, manufacturers are responsible for assuring that components, in-process, and finished devices remain within specifications. The GMP regulation requires that, after a device has been released for distribution, any failure of that device or any of its components to meet performance specifications must be investigated [21 CFR 820.162]. In addition, critical devices or components which do not meet their performance specifications must be investigated [21 CFR 820.161]. A written record of the investigation, including conclusions and followup, is required.

For medical devices and medical device software accessories that incorporate, or can be used on computing systems that incorporate, a Pentium™ processor, CDRH recommends that manufacturers conduct a hazard or safety analysis. The purpose of the analysis would be to determine whether device safety or effectiveness could be adversely affected. If the results of this analysis are negative, no further action is required beyond routine documentation of the analysis. If the analysis shows that safety or effectiveness could be affected, appropriate mitigating steps should be initiated. CDRH is aware that Intel Corporation has publicly stated they will replace Pentium™ processors free of charge.

Any questions on the Pentium™ processor should be directed to Intel Corporation. Any questions on regulatory issues concerning the Pentium™ processor should be directed to the CDRH Division of Small Manufacturers Assistance (DSMA) by fax at 301-443-8818.

Sincerely yours,



D. Bruce Burlington, M.D.
Director
Center for Devices and
Radiological Health