The Center for Ovices and Radiology (CDRM), Office of Oevlce Evaluat Ion (ODE), has reGeived a Premarket Notification vcu submitted in accor lance with Secti 510( ) of the Fe eral food, n!"lg, and CLS!r tic Ac::. (Act) for the ve ret rened product. we h.iv s:.iqned your submission a uni:: e 510(k) numbll that is citeo abcv@. Fle se refer prominently to t ls 510(k) number in any future crrenonOJence that relates to this sut tssion. we will notify you hen the processing of your premarket notification has been cmmpleted rt if u:y additIonal : .nformation. is required.

'r th e Medical Devices Act of 1990 (SMDA), signed on November 28, Rt te' hat you may not place this device into commercial d1stribution until you : ceive a letter from FDA J u-ing yo u to do so. Although the tr ditional timeframes for reviewing 510(k)s has been O days, it n w taking longer. These increas ng response times have been ueerl by many factors, including a &h rincrease in ODE's workload and ir++easi g complex device su1'jmt.10ns. During 1992, we recei-te d about t,SOO mere total submissiont; thi. we did the pre<1inCJ year. We r. troubl rl by th se increase. in (es onse timos dnd re maki g every ftort to regain predictatility n the timing ot 10(kl c vl w. Du to the increase in respon e t m as, CDRH hns established a 51U!k} Sta(Ats Reporting System through which submitters may receive a StJtus rec ..t on their 510(k) submittesGi.0Of\Si s followe:

r. aegtnning YO days after 0n::: o:ceives your 510 k) S'.Jb!lliSS.lon, you m.ly begin requesting stat.: !nformat::on. SHbmit requests v'..a fax (301-443-8618) or vf. ;::l/ to: 510(k) Status Coordnlar 5& 0 fishers Lane R(ekville arylarad 2; \WJ us.; )ecauso: . :a staft limitatlJns :a canilot "fSwec t:. -oone statu.. ; 'f. l.

:: -lu(k) Eo: >:us ..lq...ests should 1:clude: 'Il ;ubjn; ::::let' a n-lme and mai: ..g oddres; ( :: r:: :le t!r'g n .., aff"l.i:--ion with the 51l'1(k) submitte, mailingq add!tt.S!L fax nurrr,:,::: if :ipplie bl: ), telephone number, a J signature; and
Within three working days after OSMA receives a submitter's status request, OSMA will send the submitter a fax or letter that includes:

(1) the branch to which the 510(k) has been assigned;
(2) the last action, and date of that action, that CDRH has taken regarding the 510(k), e.g., logging in an amendment, preparing a decision letter; and
(3) the position of the 510(k) in the reviewer's queue.

We request that 510(k) submitters make status inquiries no more than every four weeks. We do not have the resources to respond more frequently.

The SMDA also requires all persons submitting a premarket notification submission to include either (1) a summary of safety and effectiveness information in the premarket notification submission upon which an equivalence determination could be based (510(k) summary), or (2) a statement that safety and effectiveness information will be made available to interested persons upon request (510(k) statement). Safety and effectiveness information refers to information in the premarket notification submission, including adverse safety and effectiveness information, that is relevant to an assessment of substantial equivalence. The information could be descriptive information about the new and predicate device(s), or performance or clinical testing information. We cannot issue a final decision on your 510(k) unless you comply with this requirement.

Although FDA acknowledges that the law provides the 510(k) submitter an alternative, FDA encourages 510(k) submitters to provide a 510(k) statement to FDA and to make their safety and effectiveness information available to the public, excluding confidential manufacturing process information, in lieu of submitting a 510(k) summary to the agency until FDA promulgates a regulation on the content and format of 510(k) summaries. Since the law requires that FDA make the 510(k) summary, or the source of information referred to in the 510(k) statement, publicly available within 30 days of making a substantial equivalence determination, we advise you that we may no longer honor any request for extended confidentiality under 21 CFR 807.95.

Additionally, the new legislation also requires any person who certifies that their device is substantially equivalent to a class III device to (1) certify that he or she has conducted a reasonable search of all information known, or otherwise available, about the generic type of device, AND (2) provide a summary description of the types of safety and effectiveness problems associated with the type of device and a citation to the literature, or other sources of information, upon which they have based the description (class III summary and certification). The
description should be sufficiently comprehensive to demonstrate that an applicant is fully aware of the types of problems to which the device is susceptible. If you have not provided this class III summary and certification in your premarket notification, please provide it as soon as possible. We cannot complete the review of your submission until you do so.

As of March 9, 1993, FDA has implemented the Good Manufacturing Practice (GMP) Pre-Clearance Inspection Program for all class III devices that are being reviewed under the premarket notification program. A letter of substantial equivalence cannot be sent until the finished device manufacturing site(s) and sterilization site(s) as appropriate, have been identified and FDA has determined that the manufacturer(s) is in compliance with the GMP regulation (21 CFR Part 820).

Furthermore, the new legislation, section 522(a)(1), of the Act, states that if your device is a permanent implant the failure of which may cause death, you may be subject to required postmarket surveillance. If the premarket notification for your device was originally received on or after November 8, 1991, is subsequently found to be substantially equivalent to an Aneurysm Clip, Annuloplasty Ring, Artificial Embolitation Device, Automatic Implanted Cardioverter Defibrillator System, Cardiovascular Intravascular Filter, cardiovascular Permanent Pacemaker Electrode (Lead), Central Nervous System luid Shunt, Coronary vascular Stent, Implantable Pacemaker Pulse Generator, Implanted Diaphragmatic/Phrenic Nerve Stimulator, Intracardiac Patch or Pledget, Intravascular Occluding Catheter, Replacement Heart Valve, Total Artificial Heart, Tracheal Prosthesis, Vascular Graft Prosthesis (less than 6 mm diameter), Vascular Graft Prosthesis (6 mm or greater diameter), Vena cava Clip, or ventricular Assist Device - Implant, you will be subject to the required postmarket surveillance and so notified of this determination in your substantially equivalent letter. (Some of the above listed types of devices may require a premarket approval application). This list is subject to change without notification. If you have any questions as to whether or not your device may be subject to postmarket surveillance or about this program, please contact the Postmarket Surveillance Studies Branch at (301) 594-0006.

Please note that the SMOA may have additional requirements affecting your device. You will be informed of the additional requirements as they become effective.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the Document Mail Center will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations, we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official.
If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

Lev M-

Larjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health