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September 13, 1993

MERICAN CHIN SE MEDICINE HEALTH CE
3040 CHIT.r -- LANE
SANTA CRUZ, CA 95062
ATTN: WILLIAM N LSON

510(k) Number: K934102
Receivt:d: 23-AUG-93
Product: ACUPUNCTUR!t NEEDLE

The C nter for O vices and Radiologi ! Mealth (CDRM), Offic Of oevlce Ev luation (ODE), has reGeived t e Premarket Notification vcu submitted in accoriance with Secti 510{) of the Fe erel food, n!·\1g, and CLIS!r tic AC.:. (Act} for the a· ve ret renced prcduct. we h.iv s.:.iqned your submission a uni :· e SlO(k) numbtl!that is citeo abcv@. Fle se refer prominently to t ls 510(k) number in any future crrenon0Jence that relates to this sut tssion. we will notify you hen the processing of your premarket notification has been cnmpleted rt if u:y ddition<'tl :.nformation. is required.

'rh 1.e Medical Devices Act of 1990 (SMDA), signed on November Z8, Rt te' hat you may not place this device into commercial d1stribution untl ycu : ceive a letter from FDA J u-ing VOU to do so. Although the tr ditional timeframes for reviewing 510(k)s has been Θ days, it n w taking longer. These increas ng response times have been ueerl bymany factors, including a &h rincrease in ODE's workload anrl ir•creasiogly complex device su1'jmt.10ns. During 1992, we recei·ted about t,SOO mere total submissiont; th ii. we d1d the prece<1inCJ year. We r. troub1 rl by th se increasee. in (es onse timos dnd re maki g every ftort to regain predictatility n the timing ot lO(kl c v1 ws. Du to the increase in responte t m&s, CDRH hns established a 51U!k} Sta(\ts Reportina System throush which ubmitters may receive a StJtus r:ec..Y.t on their 510(k) subntisGi.OOf>\Si s follow£:

r. aegtnning YO days after on::: o:ceives your 510 k) S'.JbJ!liSS.lon, you ml'ty begin requesting stat.: !nfarmat·:.on. SHbmit requests '-'..a fax (301-443-•861B) or v£. .:.;l..1./ to:

510(kl Status Coordlnalur
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(3) 510(k) information, including product name, SlO(k) number, date logged in by ODE (as identified in acknowledgment letter from ODE), and name of contact person identified on firm's 510(k) submission.

Enclosed is a suggested format that you may use to ensure that you include all of the required information.

- 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 the 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 SlO(k) unless you comply with this requirement.

Although FDA acknowledges that the law provides the SlO(k) submitter an alternative, FDA encourages SlO(k) submitters to provide a SlO(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 SlO(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 must 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 demon&t,ate 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 summ ry 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 Msrch 9, 1993, FDA has implemented the Good Manufacturing Practice(GMP) Pre-Clearance Inspection Program for all class III device& 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 sites(s) as appropriate, have been identified and DA has determined that the manufacturer(s) is in compliance with the GMP regulation (21 CFR Part 820}.

Furt.h rmore, the new legislation, section 522(a)(l), 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 po&tmarket 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 thn 6 mm diameter), Vascular Graft Prosthesis (6 mm or greater diameter), Vena cava Clip, or ventricular Assist D vice - Implant, you will be subject to the required po5tmarket 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). Thi 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.

Pleasnote that the SMOA may have additional requirements affecting your device. You will be informed of the&@ 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 conside ed as part of your official premarket notification submission. Because of equipment and personnel limitation$ wcannot 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 Divi ion of small Manufacturers Assistance at (301) 443-6597 or their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely you,s,

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l<larjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Ev luation
CP.nter for Devices and
Radiological Health