August 3, 2001

Dockets Management Branch (HFA-305)
Division of Management Systems and Policy, 0176 '01 AUG -9 P3:18
Office of Human Resources and Management Services,
FDA
5630 Fishers Lane, Room 1061,
Rockville, MD 20852

Subject: Comments: Medical Devices; A Pilot Program to Evaluate a Proposed Globally Harmonized Alternative for Premarket Procedures; Draft Guidance for Industry and FDA Staff; Availability

To Whom It May Concern:

The Harmonization as it is proposed brings in many benefits to large and even mid-size companies who have mature organizations and systems with ISO 9001/ISO 13481 registered manufacturing facilities and several CE marked products. **However for smaller companies and individuals this harmonization is a barrier to entry in the marketplace** because the Essential Principals have additional requirements that are not required for obtaining a 510(k). The goal of many start-ups and individuals is to develop a product, obtain a 510(k) and sell the design and 510(k) to a buyer or obtain funding from investors for future development. These start-ups and individuals will now be required to develop manufacturing capabilities and systems not currently required for 510(k) clearance well before the product is ready for commercial release. These companies and individuals under their business plan will never need to deal with European generated rules and their money making notified bodies. Following are a few things that will be enforced that are currently not required to obtain a 510(k) for a device of a relatively simple design (device with no software or complicated controls or several moving parts).

1. Total compliance to ISO 9001 and ISO 13485. Notified bodies will not permit a CE Mark without a company meeting ISO 9001 and ISO 13485. A company or individual should not be required to have systems in place such as those for adverse event reporting when there are no plans to distribute a device for clinical use. Start-ups and individuals will obtain more favorable funding after receiving 510(k) clearance and therefore to enforce such requirements earlier than necessary is a greater financial burden. A notified body would surely love to come in a year or two early to start a new revenue source for auditing and maintaining systems in facilities that are not needed at an early phase.

2. The Essential Principles require completion of manufacturing validations, life studies, aging studies, shipping tests etc. which are not currently required for a 510(k) filing which is cleared by demonstrating substantial equivalence. The cost of completion of manufacturing validations is high and will prevent an innovative start-up or an enterprising individual from designing and building test prototypes in garage type operations (which even today are the greatest innovators in the US). These requirements

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will also force the completion of final packaging design for prototype versions of the device that will never be released to production in its prototype designs. Prototypes are constructed many a times for practicality through rapid prototyping methods, without final molds and final volume manufacturing methods.

3. The need to define and maintain a full quality system to obtain a 510(k) clearance is not required in the current regulations. Today a company or individual can meet all the pertinent regulations such as design controls and obtain 510(k) clearance with very few employees or even one employee. The use of the essential principles will require more efforts than currently necessary to meet the new requirements of the Essential Principles. Harmonization will benefit organizations with mature quality systems and will limit the options to individuals and smaller start-ups with financial restrictions.

4. Why should a company or individual that has no intention of selling its products outside of the US be required to certify its system to ISO 9001 and ISO 13485? This requirement will bring additional revenue to the Conformity Assessment Body and an increased financial and systemic burden to the affected small companies and individuals.

In addition, harmonization is not in the interest of US citizens who are currently paying for cost of compliance to the Medical Device Directives in Europe whereas European companies get a free ride in the approval process in the US. US companies and individuals pay for compliance through ISO registrations, ISO audits and CE Mark approvals to notified bodies (mostly European) whereas the cost of FDA approvals and audits of European companies is paid for by US citizens. The harmonization discussions should include commercial and financial issues in addition to FDA issues (safety and effective issues) and harmonization in costs of compliance to US companies and individuals. The European Union must also allow easy, open and free access to laws, regulations and guidance documents via the worldwide web, similar to the FDA. The EU has created a compliance industry that has brought financial benefits to European countries, which must be limited to reasonable levels. EU organizations especially notified bodies must be made to write procedures and follow these procedures, which must also be available to the general public - - - similar disclosure as done by the FDA.

In summary, harmonization the way it is described in the document increases the burden on small US companies and individual designers. The FDA must require EU to provide cost free services for compliance activities it enforces or the FDA must reciprocate a charge to EU manufacturers for compliance activities such as review of 510(k)/PMA applications and audits – It is only fair in the spirit of harmonization. The FDA should not forget that it works for US Citizens and is funded by US Citizens and must look after their interests when discussing business issues.

Please feel free to contact me, if you have any questions concerning my comments at the following address.

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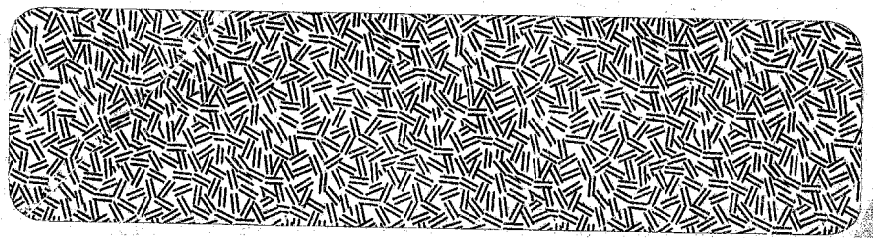

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