

510 K NOTIFICATION

From: American Chinese Medicine Health Center
3040 Childer Lane
Santa Cruz, CA 95062

Contact Person: William Nelson
Academy of Applied Quantum Bio-Technologies
(303) 388-5870

Subject: Acupuncture Needles-- Registration of Pre-1976 Marketed
Medical Device

American Chinese Medicine Health Center
3040 Childer Lane
Santa Cruz, CA 95062

July 29, 1993

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
8757 Georgia Avenue
Silver Spring, MD 20910

Attention: Document Control Clerk

Re: 510 K

Dear Sir/Madam:

The American Chinese Medicine Health Center wishes to request marketing clearance for its acupuncture needles. The pre-market notification information required is as follows:

- A. Classification Name: Acupuncture Needle
- B. Preregistration: The establishment registration number is 2938755

C. Classification: Class Two Device

D. American Chinese Medicine Health Center Federal I.D.
number is SR-ARE-15-767433

E. Labeling Promotional Material: Labeling specimen and
draft copies of promotional literature are enclosed.

Sincerely,

AMERICAN CHINESE MEDICINE HEALTH CENTER

Contact Person

William Nelson, D.Sc.

INTRODUCTION

Prior to 1976 the industry of medical devices in the United States was not regulated. The use of acupuncture needles goes back over five thousand years. Acupuncture needles were both purchased and utilized in the United States before the development of the Constitution. Acupuncture needles were definitely in commerce in the late 1800s.

In the 1976 act a condition for the grandfathering of existing devices was extended, known as the 510 K procedure.

This is a 510 K document that will prove that acupuncture needles are not experimental, but are a viable medical device. They should be labeled for proper sale and utilization.

In 1973 the FDA proposed to label acupuncture needles "experimental". This proposal was never ratified by congressional legislature. It is the point of this document that in light of today's changing medical situation, this proposal must be reevaluated. Another CDRH article (see Appendix) reverses this 1973 position. Also, in light of the 510 K legal description within the 1976 act, acupuncture needles can indeed be labeled for medical utilization (see letter in Appendix regarding legal opinion).

There are many medical techniques and devices and many products that are not totally proven effective in their utilization. The Physician's Desk Reference has many disclaimers for the products, which include disclaimers that the reason the

products work is not always known, but these items are utilized in their medical fashion. The entire system of medicine is not an exact science, but a pseudo-science; many more discoveries must be made for us to further understand the body.

All of modern medicine is a statistical evaluation of research data that is proven effective and safe enough for use by doctors. Acupuncture does indeed exceed the research and scientific criteria to find its place in modern medicine. Acupuncture does have a scientific, experimental and clinical validation. This appears in the *Quantum Biology* series (*Quantum Biology, Bio-Quantum Matrix, Quantum Vibrational Medicine, Quantum Biophysics*, and the *Quantum Energetic Medicine Dictionary*), all by Dr. William C. Nelson. These books now become an adjunct of this document.

With this in mind, the system of acupuncture, which is the oldest known system of medicine in the world today, is indeed a viable science. It is being utilized by thousands of practitioners throughout the United States. In over thirteen states there are schools and licenses for these acupuncturists. These acupuncturists are practicing an extremely old and proven study of acupuncture. They are absolutely not experimenting; they are seeing patients and working on various health concerns. Acupuncture is a licensed art taught and practiced in America. Acupuncture is not experimental.

To date, no manufacturer has prepared a proper 510 K application in accordance with the 1976 act to allow acupuncture

needles to be moved from the experimental stage and put into its proper place in the medical device category. It is the purpose of this document to correct this situation.

Acupuncture, which is recognized by the World Health Organization, is probably the largest effective medical philosophy used in the world today. Due to the large numbers of people subscribing to acupuncture in countries such as China, Japan! India, and elsewhere around the world. As such, it is due to both prejudice and bias that acupuncture has not been allowed into the modern American medicine realm. The 1973 act is irregular and inappropriate for today's practices of acupuncture.

With this document we hope to show that there are more scientific studies and more experimental validity established for acupuncture than there are for many medical arts that are already FDA-registered. It is the hope that FDA procedure, bias and prejudice will not form resistance to the purpose of this document.

The FDA system has long been stacked against acupuncture. The bias of the synthetic chemical industry has been dominant. Now is indeed the time to consider the test of time that acupuncture has met, evaluate the unbiased literature, and allow acupuncture to attain its true place within the medical arts of America.

In this document we will attempt to establish the yardstick of how a procedure becomes somewhat accepted by the medical establishment, and thereby allows for registration. That same

yardstick, when applied to acupuncture, definitely allows for acupuncture to become a registered modality, to step out of the experimental world and to take its rightful place as a medical modality.

MANUFACTURER GUIDELINES

The shaft wire used is surgical grade, stainless steel wire. The stainless steel must perform to the following criteria:

1. It must sharpen to a very fine point without fraying
2. It must polish to a smooth finish
3. It must be flexible enough to not break even if bent 180 or 360 degrees
4. It must be strong enough to not break when compacted or stretched
5. It must not rust or oxidize in any way when exposed to the air for two years or more
6. It must not have any structural defects which would weaken its strength

The formula of stainless steel used by Hwato is a Cr18Ni9 (Chromium 18, Nickel 9) stainless steel.

For the handle, technical specifications would require that the handle be both an excellent conductor of electricity (for use

with electrical stimulation) and a good conductor of heat (for warm needle technique). Handles are commonly made of solid stainless steel, stainless steel tube, wound stainless steel wire, solid aluminum and solid aluminum alloys.

TECHNICAL SPECIFICATIONS

Swiss engineering standards are used in manufacturing. Technical specifications for the two surgical grade, stainless steel wires used in the manufacture of Tai Ji brand acupuncture needles are the following Swiss engineering criteria:

1. Numbers: 1Cr18Ni9 0Cr19Ni9

2. Material and Chemical Analysis (%)

	C	Si	Mn	S	P	Cr	Ni
1Cr18Ni9	s; 0.12	1.00	s; 2.00	s 0.030	0.035	17 - 19	8 - 11
0Cr19Ni9	s; 0.06	1.00	2.00	s; 0.032	0.035	18 - 20	8 - 11

3. Mechanical Standards

	Tensile Strength (ab)	Point of Bending (a _s)	Stretching (as)	Contraction of Section (cJ)
1Cr18Ni9	∴ 55Kgf/mm ²	∴ 20Kgf/mm ²	< 45%	<:50%
0Cr19Ni9	∴ 50Kgf/mm ²	∴ 20Kgf/mm ²	∴ 45%	<: 60%

Hardness of needle body - < 450 HV_{0.2}

4. Fine of the needle surface

Tip: Ra 0.80 Pm or Rz 3.2 Pm

Body: Ra 1.6 Pm or Rz 6.3 m

COMPARATIVE 510 K PROCEDURES

Acupuncture, which has been a medical practice for over five thousand years, today in the United States boasts over thirty institutions where graduating acupuncturists can go on to state licensure. In fact, over fifteen states have official licensure of acupuncture. It is pointed out in conversations with these educational institutions that they do not view acupuncture as experimental anyway. They are not experimenting with acupuncture; they do not have any classes to teach their acupuncturists how to collect data or experiment. They teach the medical practice of acupuncture.

If it were truly experimental, as the FDA's 1973 document classified, then it would be mandatory that any practitioner tabulate his results, and then this type of data should go under the scientific scrutiny of an IRB. No IRB exists for acupuncture. Every state licensure that was reviewed also pointed out that acupuncture is not experimental in these states; it is a licensed, registered and approved medical practice. Even the CDRH has written a document saying that acupuncture should be registered and approved by the FDA (a copy of this CDRH article is contained in the Appendix).

The FDA has used experimental criteria to register other pre 1976 modalities. Some examples of these are hyperbaric oxygen, TENS, electroencephalography, and echo cardiology. We will find

that acupuncture has a thousand times more history than all of the above-mentioned items. Acupuncture has a thousand times more documentation, journal articles, and experimentation than each one of these items. There are over a thousand times as many practitioners of acupuncture as there are of the above-mentioned medical FDA registered acts combined. In fact, with whatever yardstick we choose to measure what is and is not a medical device, we will see that acupuncture needles have more research, acceptance and history than many other modalities.

The one thing that acupuncture has not had is a properly prepared 510 K for the registration of acupuncture needles. That is the purpose of this document. A list of the institutions teaching acupuncture and a list of the states licensing acupuncture are also contained in the Appendix.

It must also be pointed out that the FDA's purpose in the 1976 Device Act is to register those items prior to 1976 through the grandfathering process of the 510 K. It is not the job of the FDA to interpret what is and is not medicine; that is a state issue. Many states have already licensed acupuncture as a non-experimental, medically-valid therapy.