Why the Sale of Old Indigos is Illegal

Let me explain why the sale of old Indigos is not legal. First they have been given a cease and desist from BHO who has the only working software. In Canada and Europe they have been given a cease and desist from selling or marketing as they lost all registration. In Mexico they do not have any registration at all. The past Mexican sales were piggybacked onto the legal SCIO system. But now the cease and desist from the owners of the software makes sale of the old indigo into Mexico illegal. Copyright theft, criminal circumvention of traceability database, circumvention of a cease and desist from the holders of the trademark, copyright, source code, validation and verification.

In America it is illegal to sell a biofeedback system that does not have proper ISO code traceability. Only the BHO software has the proper validation. The hacked illegal version of the 12-12-12 system is now illegal to activate and all must get the 2013 version from BHO. SCIO International is backing us up all the way on this issue. But even without them SCIO International has nothing to do with USA or Mexico. So Gages is lying on her posts. SCIO international cannot circumvent BHO and they are adamant to stop the old indigo.

So, new sales anywhere in the world are not possible. It is criminally illegal to sell. And if you buy such a device it will be illegal to use and could be confiscated and if used on a patient you could be charged with a crime. The old indigo is made with an inferior design and inferior products such as chips and harness. Comments of the superiority of any part of the Indigo are just not true.

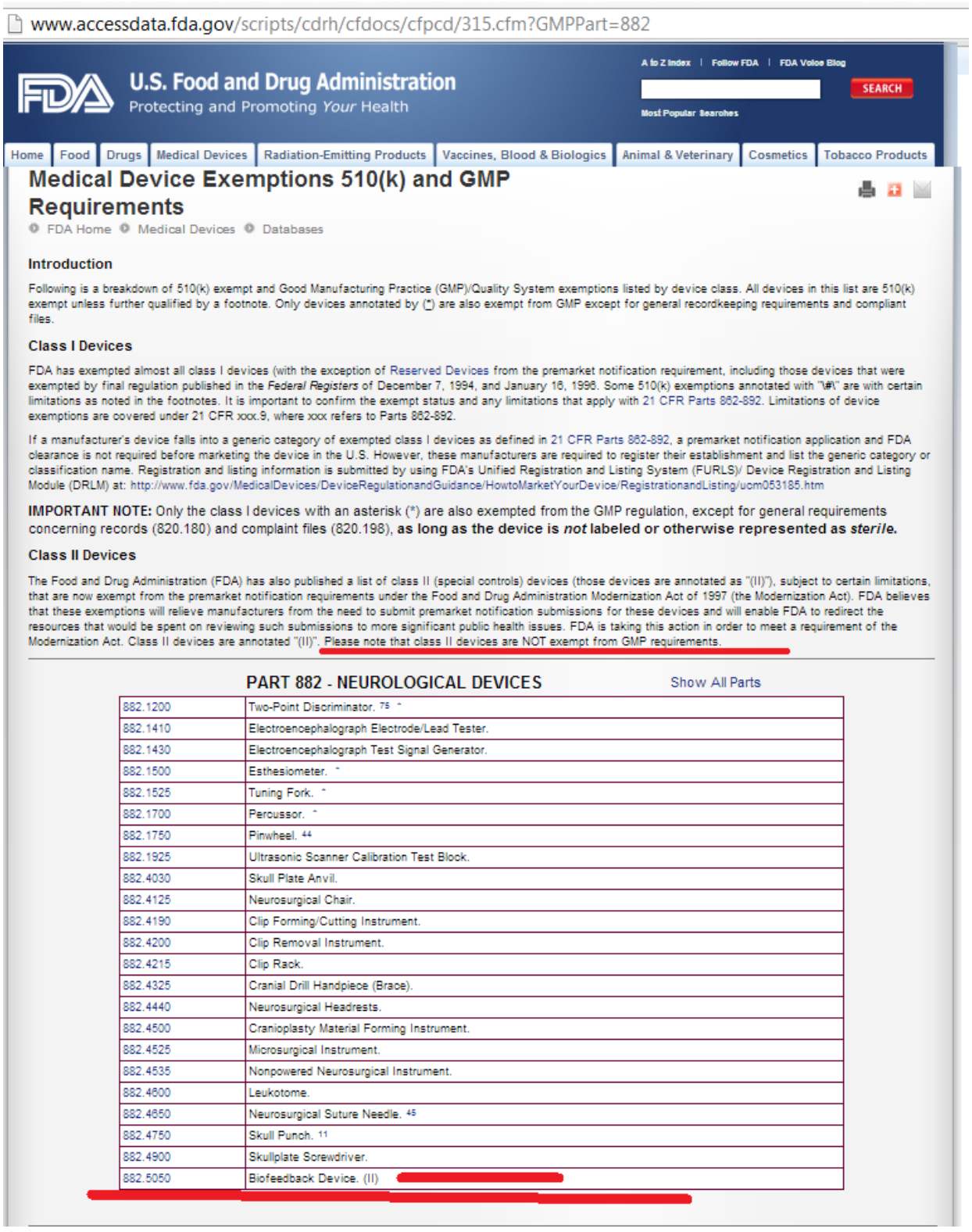
Francisco's software is just illegal, fraudulent and dysfunctional anywhere.

BHO working with NSY have a FDA establishment number, a registered clinical evaluation and a 510k. QWV has a false shell office bogus establishment registration. QWV has no 510k, no clinical evaluation and no permission to market and sell in America. The FDA establishment office has to be an inspectable office of GMP records not a bogus shell. QWV have no registration to sell anywhere in the world. And yet they are continuing to sell a bogus illegal counterfeit system that Ken has admitted is criminal.

If you read this document (Medical Device GMP requirements, see appendix, especially what is underlined in red) you can see that any biofeedback device still must have full GMP requirements , we have ours in the proper clinical evaluation and studies and a 510k, ask QWV for their GMP folder and when they say they don't have one or if they ask what that means, then perhaps you can all see that they have nothing , nada zip and then you can see they have no respect for the law. Do you think anyone at QWV knows what GMP means, SOP, have any of them read the 211 CFRs????Does anyone have any confidence in QWV at all??? Does anyone respect the Law.

Several police reports against Gage, Ken, Mike Russell, and Brian Thompson for stealing money are accumulating. It is amazing that someone would still believe in these people. It is amazing how stupid people can be to believe that these people have any clue about what they do. But these crooks are hoping to dupe there are new people who do not know about the criminal activity of TQA +QWV after a

cease and desist. This is why we must give a warning to the authorities about any seminar they are doing or attending. This message is a warning to all who might be duped or conned into buying something an old indigo. Appendix:



www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/315.cfm?GMPPart=882

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Medical Device Exemptions 510(k) and GMP Requirements

FDA Home › Medical Devices › Databases

Introduction

Following is a breakdown of 510(k) exempt and Good Manufacturing Practice (GMP)/Quality System exemptions listed by device class. All devices in this list are 510(k) exempt unless further qualified by a footnote. Only devices annotated by (*) are also exempt from GMP except for general recordkeeping requirements and compliant files.

Class I Devices

FDA has exempted almost all class I devices (with the exception of Reserved Devices from the premarket notification requirement, including those devices that were exempted by final regulation published in the *Federal Registers* of December 7, 1994, and January 18, 1996. Some 510(k) exemptions annotated with "\#\" are with certain limitations as noted in the footnotes. It is important to confirm the exempt status and any limitations that apply with 21 CFR Parts 862-892. Limitations of device exemptions are covered under 21 CFR xxx.9, where xxx refers to Parts 862-892.

If a manufacturer's device falls into a generic category of exempted class I devices as defined in 21 CFR Parts 862-892, a premarket notification application and FDA clearance is not required before marketing the device in the U.S. However, these manufacturers are required to register their establishment and list the generic category or classification name. Registration and listing information is submitted by using FDA's Unified Registration and Listing System (FURLS)/ Device Registration and Listing Module (DRLM) at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053185.htm

IMPORTANT NOTE: Only the class I devices with an asterisk (*) are also exempted from the GMP regulation, except for general requirements concerning records (820.180) and complaint files (820.198), **as long as the device is *not* labeled or otherwise represented as *sterile*.**

Class II Devices

The Food and Drug Administration (FDA) has also published a list of class II (special controls) devices (those devices are annotated as "(II)"), subject to certain limitations, that are now exempt from the premarket notification requirements under the Food and Drug Administration Modernization Act of 1997 (the Modernization Act). FDA believes that these exemptions will relieve manufacturers from the need to submit premarket notification submissions for these devices and will enable FDA to redirect the resources that would be spent on reviewing such submissions to more significant public health issues. FDA is taking this action in order to meet a requirement of the Modernization Act. Class II devices are annotated "(II)". Please note that class II devices are NOT exempt from GMP requirements.

PART 882 - NEUROLOGICAL DEVICES

Show All Parts

882.1200	Two-Point Discriminator. [75] *
882.1410	Electroencephalograph Electrode/Lead Tester.
882.1430	Electroencephalograph Test Signal Generator.
882.1500	Esthesiometer. *
882.1525	Tuning Fork. *
882.1700	Percussor. *
882.1750	Pinwheel. [44]
882.1925	Ultrasonic Scanner Calibration Test Block.
882.4030	Skull Plate Anvil.
882.4125	Neurosurgical Chair.
882.4190	Clip Forming/Cutting Instrument.
882.4200	Clip Removal Instrument.
882.4215	Clip Rack.
882.4325	Cranial Drill Handpiece (Brace).
882.4440	Neurosurgical Headrests.
882.4500	Cranioplasty Material Forming Instrument.
882.4525	Microsurgical Instrument.
882.4535	Nonpowered Neurosurgical Instrument.
882.4600	Leukotome.
882.4650	Neurosurgical Suture Needle. [45]
882.4750	Skull Punch. [11]
882.4900	Skullplate Screwdriver.
882.5050	Biofeedback Device. (II)