



'APR 23 2009

Mr. William Cone
Regulatory Affairs
Consolidated Technologies, Inc.
2170 Woodward, Suite 100
Austin, Texas 78744-1832

Re: k961912

Trade/Device Name: Qualitrol, Alpha Fetoprotein (AFP) Control Set
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control materials (assayed and unassayed)
Regulatory Class: I
Product Code: JJY
Dated: July 26, 1996
Received: July 29, 1996

Dear Mr. Cone:

This letter corrects our substantially equivalent letter of August 15, 1996.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other

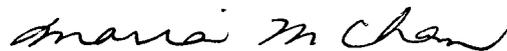
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Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Immunology and Hematology Devices at (240) 276-0493. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to <http://www.fda.gov/cdrh/mdr/>.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and
Safety
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K961912

Device Name: Qualitrol AFP Control Set

Indications For Use:

Clinical laboratories, performing quantitative or semi-quantitative tests to determine alpha fetoprotein (AFP) in patient specimen and desiring to use the quality control material that is not provided with the kit used for such measurement, may use Qualitrol AFP Control Set as an alternative. Compattibility among the test reagents and Qualitrol AFP Control Set needs to be established prior to such a use.



(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K961912

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)

