



November 12, 1999

Mr. Fredrick Sturtz
U.S. NRC
Mailstop T8F5
11545 Rockville Pike
North Bethesda, MD 50852

Dear Mr. Sturtz:

I am writing you after speaking with Mr. Tony Kirkwood of your office on November 9, 1999. Metorex has discovered that the SUPS probe, which was registered as part of the Model 880 Analyzer in the past by Metorex's predecessors but appears to have been dropped as the registrations were revised and reissued to the succeeding distributors, is not included in Metorex's current registration and distribution license. Consequently, some previous distributions of the SUPS probe appear inconsistent with our license. We wish to correct this discrepancy as quickly as possible.

The SUPS probe was developed in the 1970's and covered by the Columbia Scientific Instruments registration for the 880, TX227D101G dated August 12, 1988 (Enclosure 1). The safety evaluation that was performed in 1979 is also enclosed (Enclosure 2). This registration and safety evaluation covered a family of probes including the HEPS, LEPS and SUPS, which were sold with the Model 880 Analyzer. Because the registration covered the analyzer and probes together, the SUPS probe was not named separately, but was described in text near the bottom of page 2 (the statement "...the shutter activating knob is depressed by placing the probe on the surface to be measured..." is understood to refer to this probe). In 1988, the registration of these probes was transferred to Princeton Gamma-Tech, Inc (PGT). The PGT registration, NR-551-D-104-B for the 820, 840 and 880 (Enclosure 3) refers to the Surface Analyzer Probe, which may have been intended to refer to this SUPS probe, or to the newer (at the time) SAPS probe which was added to the product line to replace the SUPS or both. There were a number of amendments and changes to the registration until the April 21, 1993 registration, NR-701-D-101-G (Enclosure 4), when the name of the analyzer was deleted and the specific probe names were registered. Although the SUPS was one of the original probes and was still being distributed at the time, it was not included among the probes specifically listed. Because of changes in personnel, we have been unable to determine why it was omitted. This last registration was issued to Outokumpu Electronics Inc. Outokumpu has since been succeeded by Metorex as the listed distributor and the registration has been further amended to reflect the change. Our




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license authorizes the distribution of the probes identified on the current registration, though it also continues to authorize the model 880 analyzer which originally included the SUPS probe.

Our records indicate that SUPS probes were sold in the 1991 to 1998 time frame and that 15 units are currently possessed and used by three customers. At this time, I would request your guidance on the appropriate actions we should take. Can our registration statement and distribution license be amended, based on the original registration, to restore the SUPS probe to the list of devices we are authorized to distribute, or is a further application necessary? In the interim, what actions should we take with respect to customers currently possessing these devices?

If you have any questions, please contact me at (609) 406-9000, ext. 122 or by email at John.Patterson@MetorexUSA.com. I would like to resolve this matter as quickly as possible.

Sincerely,



John I.H. Patterson, Ph.D.
President

JHHP/jlr

REQUEST FOR A SEALED SOURCE OR DEVICE EVALUATION

INSTRUCTIONS: Send this request AND a copy of all related letters/applications and drawings to the Chief, Sealed Source Safety Section, OWFN Mail Stop O-6 H3. Change the License Tracking System milestone to 19 and assign to reviewer code 1-5.
NOTE: Retain a copy of this request with the application and background files.

REQUESTER Metorex		REGION/LOCATION: <input type="checkbox"/> I <input type="checkbox"/> II <input type="checkbox"/> III <input type="checkbox"/> IV <input type="checkbox"/> HQ <input type="checkbox"/> LFARB	
TELEPHONE NUMBER 609-406-9000	DATE 	TYPE OF ACTION REQUESTED (Check as appropriate) <input type="checkbox"/> SOURCE REVIEW <input checked="" type="checkbox"/> AMENDMENT OF REGISTRATION SHEET NUMBER(S) <input type="checkbox"/> DEVICE REVIEW <input type="checkbox"/> CUSTOM REVIEW	
NAME OF APPLICANT John I. H. Patterson, Ph.D.			
MAIL CONTROL NUMBER(S) 			
LETTER/APPLICATION DATE 11/12/1999	LICENSE NUMBER(S) 		

COMMENTS:
Princeton Crossroads Corporate Center
250 Phillips Boulevard
Ewing, NJ 08618

FOR SSSS USE ONLY		
REVIEWER Ujagar Bhachu	MODEL NUMBERS 880, 820, 840, HEPS	NUMBER ASSIGNED 99-63
DATE RECEIVED 11/18/1999	DATE ASSIGNED 11/18/1999	DATE TO FEES 11/18/1999

TYPE OF ACTION (Indicate the number of each type)			
<input checked="" type="checkbox"/> COMMERCIAL DISTRIBUTION (FORMAL)		<input type="checkbox"/> USE BY A SINGLE APPLICANT (CUSTOM)	
SOURCE (9C) <input type="checkbox"/> NEW <input type="checkbox"/> AMENDMENT	DEVICE (9A) <input type="checkbox"/> NEW <input checked="" type="checkbox"/> AMENDMENT	SOURCE (9D) <input type="checkbox"/> NEW <input type="checkbox"/> AMENDMENT	DEVICE (9B) <input type="checkbox"/> NEW <input type="checkbox"/> AMENDMENT
<input checked="" type="checkbox"/> NO SAFETY EVALUATION REQUIRED <input type="checkbox"/> NO FEES REQUIRED		<input type="checkbox"/> LICENSING ACTION REQUIRED (IF KNOWN) <input type="checkbox"/> YES <input type="checkbox"/> NO	
<input type="checkbox"/> OTHER (Specify) 			

	TOTAL NUMBER OF REVIEW HOURS	NOTES Amendment to TX-227-D-101-G, NR-551-D-104-B, NR-701-D-101-G.
	NUMBER OF DEFICIENCY LETTERS	
	NUMBER OF DEFICIENCY CALLS	

FOR FEE USE ONLY			
TYPE OF FEE		FEE CATEGORY <input type="checkbox"/> 9A <input type="checkbox"/> 9B <input type="checkbox"/> 9C <input type="checkbox"/> 9D	
AMOUNT RECEIVED	CHECK NUMBER	DATE OF CHECK	LOG
APPROVED BY			DATE OF RETURN

COMMENTS



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President

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