

B.E.

MEYERS

& CO. INC.
ELECTRO OPTICS

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July 12, 2000

Dockets Management Branch (HFA-305)
Food & Drug Administration
Rm 4-26
Parklawn building
5600 Fishers Lane
Rockville, MD 20857

Subject: Request for variance for Class IIb requirements for the IZLID Series laser products noted in this letter.

Dear Director,

On September 29, 1999 we filed a product report with the CDRH for the IZLID Series Models #424, 424P-50, 424-100, 424P, 425P & 428P-400 lasers, Accession #9922124.

The IZLID series lasers model #424, 424P-50, 424-100, 424P, 425P & 428P-400 are Class IIb Infrared Laser Illuminator/Designator devices.

Therefore, in accordance with 21 CFR 1010.4, B.E. Meyers & Co. Inc. formally requests a variance from 1040.10(f) (3) & (4), 1040.10(f)(5)(ii) and 1040.11(b) based on the following information.

21 CFR 1040.10(f) (3) & (4):

The IZLID series devices incorporate an Interlock Plug and Receptacle that would serve the function of both the Remote Interlock Connector and the Key Switch within the intent of the regulations. The Interlock Plug requires a contact closure across it to complete the electrical path to activate the laser. The Interlock Plug is a unique multi-pin plug that is removable from the devices. When this key is removed the laser cannot function. Having these two features built into one component allows law enforcement officers to efficiently arm the laser when performing their duties without compromising safety.

21 CFR 1040.10(f)(5)(ii):

The IZLID series devices incorporate an emission indicator LED on each of the units. The LED comes on and Laser emission occurs without any delay once the normally OFF/momentary ON pressure switch is activated. The user is aware of the imminent emission of laser energy as this is initiated by the user manually holding down a momentary switch. Since the IZLID series devices mount on various weapons for use as an aiming device, any delay in laser emission could compromise the safety of the law enforcement officers in performance of their duties.

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21 CFR 1040.11(b):

We have recently learned that Designator lasers fall under the requirements of 1040.11(b) Surveying, Leveling and Alignment laser products. The IZLID series lasers model #424, 424P-50, 424-100, 424P & 425P are Class IIIB Infrared Laser Illuminator/Designator devices that project an infrared laser beam, which cannot be seen with the naked eye but can be seen with night vision devices. These devices are vital tools required by our government, military & law enforcement agencies to conduct surveillance operations at night without compromising the safety of law enforcement officers.

Note: The Model #428P-400 submitted in the September 29, 1999 product report is an illuminator only laser and does not require the 1040.11(b) variance.

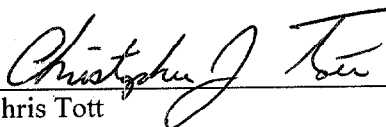
We believe that these infrared aiming laser devices utilize alternate means for providing radiation safety or protection equal to that provided by products of similar design meeting all the requirements of the standard and/or that the specified requirements are not appropriate for laser products for this intended use.

The intended use of this product is by government, Military and law enforcement agencies for their routine execution of duties. B.E. Meyers & Co. Inc. will restrict the sale of the IZLID series, Laser Illuminator/ Designator products noted above to government, military & law enforcement agencies, including law enforcement personnel.

The requested period of time the variance would be in effect is 5 years.

If you have any questions or need more information in order to process this variance request, please do not hesitate to contact me.

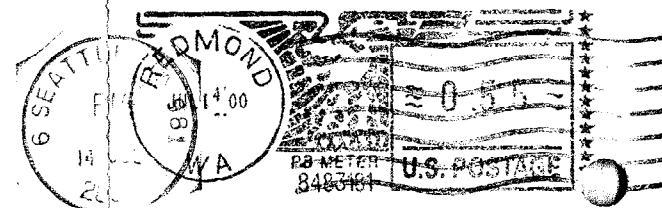
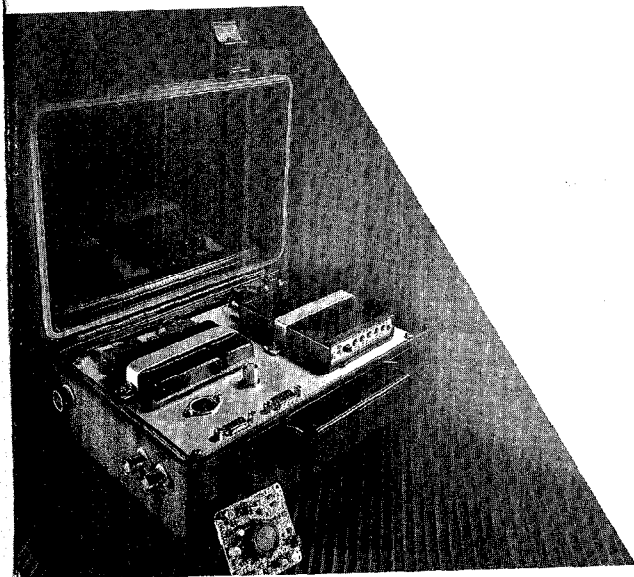
Sincerely,


Chris Tott
Production Engineer



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