GLOCK, Inc. U.S.A.

PERFECTION

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Center for Devices and Radiological Health
Office of Compliance (HFZ-300)
Attn. Electronic Product Reports
2098 Gaither Road
Rockville, MD 20850

your reference	dated	our reference	Smyrna,
			30-November -2004

Reference: Variance Application

Dear Sir or Madam,

Find enclosed the application for a variance from certain requirements of 21 CFR 1040.10 for the following devices:

- GLOCK TACTICAL LIGHT MODULE GTL 51
- GLOCK TACTICAL LIGHT MODULE GTL 52

We are submitting this variance application as required by 21 CFR 1010.4.

Please, let me know if you require any additional information to approve this request so we can begin importation of these devices into the United States.

Best Regards,

Carlos A. Guevara
GLOCK, Inc.
Legal Department

2005V-0206

GLGE H0029 22-3 VAR1

OLLinger-01

GLOCK Ges.m.b.H. AUSTRIA

PERFECTION

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2098 Gaither Road
Rockville, MD 20850

Ihr Zeichen your reference	Ihre Nachricht dated	Unser Zeichen our reference	Deutsch-Wagram, 16-Nov-2004

Dear Sir or Madam,

following § 1010.4 of 21 CFR we hereby apply for approval of a variance from certain requirements of 21 CFR 1040.10 as detailed below. Following the limited level of hazard of both the visible and the infrared laser beam (both Class 3R according to IEC 60825-1), we apply for unlimited distribution within the USA.

Manufacturer:
GLOCK Ges.m.b.H., Austria

Product for which variance is requested:
Glock tactical light Model GTL 51 and Model GTL 52

Product description:
GTL 51 and GTL 52 are laser pointer aiming aids that can be attached to pistols. They emit a visible laser beam (< 5 mW, Class 3R according to IEC 60825-1 Ed1.2, Class IIIa according to CFR 1040) and a near-infrared beam (< 1.5 mW, Class 3R according to IEC 60825-1 Ed 1.2, Class IIIb according to CFR 1040).

The difference between GTL 51 and 52 is that for GTL 51, the light output is fixed to the maximum level, while for GTL 52, the output of the visible Flashlight and the infrared laser can be dimmed, otherwise the two models are identical.

The visible and infrared laser beam can not be emitted at the same time, i.e. either the visible or the infrared beam is selected for emission prior to switching the GTL into operation.

Variance requested for 21 CFR requirement
21 CFR 1040.11 (b) restricts the class of alignment laser products such as the GTL 51 and 52 to Class IIIa, Class II, or Class I.

The products are designed to comply with all other applicable provisions as stated in 21 CFR with consideration of Laser Notice 50. However, we also apply for approval of a shorter text for the certification label on the product, as described further below.

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Description of deviation and safety level:

Since Class IIIa of CDRH CFR 21 is currently defined for the visible wavelength range only, the near-infrared beam output level of 1.5 mW places the product into Class IIIb, as it exceeds the AEL of Class I. IEC 60825-1, however, defines Class 3R also in the infrared wavelength range where the time base is 100 s and the accessible emission is limited to less than 5 times the AEL of Class 1. The product, according to IEC 60825-1 is Class 3R, also for the infrared beam.

As the purpose of the infrared laser pointer is to serve as aiming aids to be viewed with night vision equipment, restriction to output levels to less than the AEL of Class 1 would produce a beam which could not be properly seen. Although the output level of the infrared beam of 1.5 mW exceeds the AEL of Class 1 (which is determined for a time base of 100 s), it is noted that this level is safe for ocular exposures for exposure durations of up to 1 s. The emission level of 1.5 mW compares to the emission limits as specified in IEC 60825-1 in the following way (wavelength: 855 nm, small source limits):

Limit	*time base*	*Limit value*	*Ratio: emission of 1.5 mW to limit value*
AEL Class 1	100 s	0.8 mW	Limit exceeded by factor 1.9
AEL Class 3R	100 s	4.0 mW	Emission lower than limit by factor 2.7
MPE (power through 7 mm aperture)	0.9 s	1.5 mW	Emission less than MPE for appr. 1 s exp dur.

According to IEC 60825-1 classification, the infrared laser beam would be Class 3R, however, it should be noted that the time base for the infrared wavelength range is 100 s. For shorter time base values (shorter exposure durations), the allowed limit is higher, so that for an emission level of 1.5 mW, the MPE for the eye is exceeded only for exposure durations of longer than about 1 second, and the emission (exposure) is below the MPE for exposure durations of less than that.

For the given product which is hand held and used as a laser pointer over some distance, it is unlikely that the highly collimated and small diameter beam passes through the pupil of the eye for more than 1 second, so that for all but intentional viewing of a person pointing the beam into his/her eye for extended period of times, the exposure is safe, i.e. below the MPE. Compared to the level of safety which is associated with a visible Class IIIa laser, where the MPE can be exceeded by up to a factor of 5 for a time base of 0.25 s, the hazard presented by the infrared beam is a lot smaller.

Additional safety features of product

Double action switch on	There are two switches to operate the laser: a pre-selector switch to select the type of emission –this pre-selector switch is usually in the "0" position and only moved to another position briefly before emission is needed (in other positions, battery power is drained even if the emission is not switched on). The actual emission is switched on with the main switch. When the pre-selector switch is in the "0" position, operating the main switch does not initiate any emission. This double action switch on helps to prevent unintentional emission.
Emission indicator for IR as required by IEC 60825-1	When emission of the infrared laser beam is initiated, a small green LED indicates the emission

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Certification label text

According to Laser Notice 50, one version of the required certification text would be

> Complies with 21 CFR 1040.10 and 1040.11 except for deviations pursuant to Laser Notice No. 50, dated July 26 2001

Following the variance approval, reference to the variance is also to be made on the certification label. Reference to both the Variance and Laser Notice 50 would make the text too long to fit on the label. We therefore apply for approval of the following text on the certification label on the product:

> Complies with 21 CFR 1040 except as authorized by Variance XXXXX

Due to the limited size of the product and thus of the label, it is necessary to keep the text as short as possible in order to keep this text and the safety relevant text on the label (class, aperture, wavelength, power) legible (see manual page 13 and 14 for an image of the complete label of the product, incorporating all necessary information and labels following IEC 60825-1 and 21 CFR 1040).

The variance is identified by its number, so that we would like to apply for a reference to the variance number only without adding the date, the sake of improved readability, as otherwise, the font size of the full text would have to be reduced to also fit in the "effective Date".

Since we apply for the text of the certification label in this application for variance, the somewhat shorter text would be part of the approval and thus reference to the Variance would take precedence over a reference to both the Laser Notice 50 and the Variance, as reference to the Variance would also implicitly include deviations pursuant to Laser Notice 50.

The complete information including the effective date of the Variance is contained in the Supplement Info (Attachment B2) and the manual (Attachment B1).

Desired termination date of variance not before

December 31st 2009

Number of units to be manufactured within effect of variance

50.000 units

Duly signed

GLOCK Ges.m.b.H.

R. Hirschheiter

GLOCK Ges.m.b.H.
Nelkengasse 3
A-2232 Deutsch-Wagram
AUSTRIA

J. Kroyer

Enclosure: 3 set of documents