

Section 3 – 510(k) Cover Letter

March 16, 2015

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

RE: Traditional Premarket Notification
Shift Labs – DripAssist

Dear Sir/Madam:

This document is a 510(k) Cover Letter following the format recommended in the guidance document “Format for Traditional and Abbreviated 510(k)s” issued on August 12, 2005. Please note that [REDACTED] is a regulatory consulting company that is serving as the contact for the submission sponsor – Shift Labs. This submission consists of one paper copy and one eCopy, which is an exact duplicate of the paper copy.

Administrative Information

- Type of submission: Traditional 510(k)
- Common name: IV drip rate monitor
- 510(k) submitter: Shift Labs
[REDACTED]
- Contact person
[REDACTED]

- Confidentiality Shift Labs requests that FDA keep confidential the information in this submission in accordance with 21 CFR 807.95(b). Some of this information is proprietary and is nondisclosable under the Freedom of Information Act even after the existence of the submission becomes public.
- Classification regulation CFR 880.2420
- Class Class II
- Panel General Hospital
- Product code FLN – Electronic monitor for gravity flow infusion systems
- Related FDA documents None

Basis for Submission

New device.

Design and Use of the Device

Question	Yes	No
Is the device intended for prescription use (21 CFR 801 Subpart D)?		
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		
Does the device contain components derived from a tissue or other biologic source?		
Is the device provided sterile?		
Is the device intended for single use?		
Is the device a reprocessed single use device? If yes, does this device type require reprocessed validation data?		
Does the device contain a drug?		
Does the device contain a biologic?		
Does the device use software?		
Does the submission include clinical information?		
Is the device implanted?		

Please contact [REDACTED] for any questions regarding this submission. The fax number is [REDACTED] and email address is [REDACTED]

Sincerely,

Copy: Beth Kolko, PhD
CEO, Shift Labs

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 6 - Traceability matrix
 7 - Verification and validation

C [REDACTED]

D [REDACTED]