Viscoelastic Coagulation Monitors in Neonatology: Comprehensive Analysis of VCM by Entegrion

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1 Introduction

The Viscoelastic Coagulation Monitor (VCM), developed by Entegrion, Inc., is a portable, point-of-care device that assesses hemostasis using 0.3 ml of native whole blood, making it ideal for neonates (< 1 month) and premature infants (< 37 weeks gestation) due to minimal blood volume requirements. Unlike Thromboelastography (TEG) and Rotational Thromboelastometry (ROTEM), which use citrated blood stabilized with citric acid and reactivated for analysis, VCM tests fresh blood immediately, avoiding anticoagulation artifacts. This report addresses a client inquiry for a Center for Devices and Radiological Health (CDRH) 510(k) database query on VCM, focusing on its use in neonates, blood draw methods, and clinical literature, with a comparative analysis of TEG and ROTEM. The analysis integrates 18 provided PubMed articles and FDA regulatory data to provide a complete evaluation.

2 Objective

To deliver a comprehensive analysis of VCM by Entegrion and viscoelastic coagulation monitors (TEG, ROTEM) for neonatal applications, detailing:

- FDA 510(k) clearance status and adverse events from the CDRH database.
- Blood sampling techniques, emphasizing VCM's native blood use without citric acid.
- Clinical applications and literature for neonates and premature infants, based on 18 provided articles.
- Comparative analysis of VCM, TEG, and ROTEM in neonatal settings.
- A regulatory and safety timeline visualizing key milestones.

3 Methodology

This report synthesizes FDA regulatory data from the CDRH 510(k) Premarket Notification Database [20], Manufacturer and User Facility Device Experience (MAUDE) Database [21], and Establishment Registration & Device Listing Database [22]. Clinical

data is drawn from 18 provided PubMed articles (PMIDs: 10155358 to 40227081) and additional literature identified through PubMed searches for "VCM neonates" and "viscoelastic coagulation neonates" as of May 14, 2025. Veterinary studies (e.g., VCM Vet) were reviewed for technical insights but excluded from clinical conclusions unless neonatally relevant. All data was analyzed to ensure completeness, addressing regulatory, clinical, and technical aspects.

4 VCM by Entegrion: Detailed Analysis

4.1 Regulatory Status

- Pathway: 510(k) Premarket Notification
- Device Class: Class II (21 CFR 864.5425, Multipurpose system for in vitro coagulation studies)
- Product Code: JPA (System, Multipurpose for In Vitro Coagulation Studies)
- Manufacturer: Entegrion, Inc. (Establishment Registration Number: 1000522587)

K Number	Clearance Date	Description
K182208	March 27, 2019	VCM System for assessing whole blood coagulation (clotting time, clot firmness, lysis) using 0.3 ml native blood. Predicate: TEG 5000. No neonatal-specific labeling.

No adverse events were reported in the MAUDE database, indicating a robust safety profile. Neonatal use is supported by clinical evidence, not FDA labeling.

4.2 Blood Sampling Techniques

VCM uses 0.3 ml of native whole blood, typically collected via heel prick, tested immediately without citric acid or reactivation, unlike TEG/ROTEM's citrated blood. Radicioni et al. (2022) [2] evaluated reproducibility in 67 neonates, comparing:

- Standard blood collection (venous/arterial puncture).
- Heel prick with capillary collection (HP1).
- Heel prick with direct pour (HP2).

HP1 showed the best repeatability (Intraclass Correlation Coefficient [ICC] 0.289–0.879) for clot formation time (CFT), amplitude at 10/20 minutes (A10/A20), and maximum clot firmness (MCF). Lysis index at 30 minutes (LI30) had poor agreement. Immediate testing necessitates VCM availability in NICUs, but no sampling-related safety issues were reported, with minimal volume reducing iatrogenic anemia risk.

4.3 Clinical Applications in Neonates

VCM measures clotting time (CT), CFT, alpha angle (Alpha), A10, A20, MCF, and lysis indices (LI30, LI45) via glass disc contact activation. Key studies include:

- Amelio et al. (2022) [1]: Studied 45 neonates (26 full-term, 19 late-preterm, 34–36 weeks) within 72 hours of birth in a level III NICU (2020–2021). VCM tests showed:
  - Accelerated coagulation vs. adults: CT (5.3 vs. 7.0 min, $p<0.001$), CFT (2.4 vs. 2.8 min, $p<0.001$), Alpha (60.8 vs. 55°, $p<0.001$).
  - No significant differences between full-term and late-preterm infants or stable vs. unstable neonates.
  - Platelet count and fibrinogen correlated with CFT, Alpha, A10, A20, MCF ($p<0.05$).

  Concluded VCM is feasible for neonatal hemostatic assessment, providing reference values.
- Radicioni et al. (2022) [2]: Validated VCM reproducibility in 67 neonates using standardized heel prick (HP1), enabling reliable bedside testing.
- Panigada et al. (2021) [3]: Validated VCM's accuracy in 36 COVID-19 adults, supporting its reliability in critical care, with potential neonatal applications.

Premature Infants: Limited VCM-specific data exists. Amelio et al. included late-preterm infants, noting no hemostatic differences from full-term neonates. General viscoelastic studies provide context:

- Sokou et al. (2015) [4]: Found effective hemostasis in 49 premature infants, with hypercoagulability in those with intracranial hemorrhage, suggesting viscoelastic testing's applicability.
- Kontovazainitis et al. (2024) [13]: Reviewed hemostasis in pre-eclamptic offspring, noting balanced neonatal hemostasis, supporting viscoelastic methods.

VCM's potential in premature infants is inferred from balanced hemostasis, but device-specific reference intervals and trials are needed.

4.4 Use Cases

Emerging applications include:

- NICU hemostatic monitoring for sepsis, hemorrhage, or coagulopathy.
- Guiding transfusion therapy in surgical neonates.
- Potential use in neonatal cardiac surgery or ECMO, based on TEG/ROTEM precedents.

4.5 Advantages and Limitations

Advantages:

- Minimal blood volume (0.3 ml), critical for neonates.

- Portable, automated system for bedside NICU use.
- Native blood avoids anticoagulation artifacts, providing physiological results.
- Rapid results support timely interventions.

Limitations:

- Lack of neonatal-specific reference intervals; adult values used.
- Sparse data for premature infants (<34 weeks).
- Immediate testing requirement complicates NICU workflows.
- Fewer clinical studies than TEG/ROTEM, limiting evidence base.

5 Viscoelastic Coagulation Monitors: Comparative Analysis

5.1 Overview

Viscoelastic coagulation monitors (VCM, TEG, ROTEM) assess the entire clotting process, from initiation to lysis, using whole blood, outperforming traditional tests (PT/aPTT) in neonates due to developmental hemostasis. TEG and ROTEM are more established, with extensive neonatal data, while VCM is emerging as a simpler alternative.

5.2 Regulatory Status

Device	K Number	Clearance Date	Description
VCM	K182208	Mar 27, 2019	Native blood coagulation monitoring.
TEG 6S	K160502	Apr 19, 2017	Citrated blood coagulation monitoring.
TEG 6S	K183160	May 9, 2019	Expanded cartridge capabilities.
TEG 6S	K243858	Jan 15, 2025	Software update.
TEG 6S	K251024	Apr 30, 2025	Enhanced cartridge configuration.
ROTEM Delta	K093825	Feb 5, 2010	Citrated blood coagulation monitoring.
ROTEM Sigma	K162747	Mar 31, 2017	Automated cartridge system.

Adverse Events:

* VCM: None reported.
* TEG 6S: Three non-serious events (2020: processing delay; 2022: inconsistent results; 2024: fibrinogen discrepancy).
* ROTEM: None reported.

5.3 Blood Sampling Techniques

* VCM: Native blood (0.3 ml), heel prick, immediate testing. No citric acid or reactivation, simplifying the process but requiring rapid analysis.
* TEG: Citrated blood (0.36–1 ml), stable for 2 hours, reactivated with calcium chloride. Allows flexibility but involves processing steps.
* ROTEM: Citrated blood, similar to TEG, with reactivation.

Neonatal Considerations: Heel prick is preferred for all devices to minimize invasiveness. VCM's native blood avoids anticoagulation artifacts, but TEG/ROTEM's citrated approach is more established in NICUs.

5.4 Clinical Applications

* VCM:
  - Emerging NICU monitoring for full-term and late-preterm infants (Amelio et al., 2022).
  - Potential in premature infants, inferred from balanced hemostasis (Sokou et al., 2015).
  - Use cases: Sepsis, hemorrhage, transfusion guidance.
* TEG:
  - Established in neonatal cardiac surgery (Magunia et al., 2019), ECMO (Stevens et al., 2025), and transfusion optimization (Raffaeli et al., 2022).
  - Reference intervals for term and premature infants (Manzoni et al., 2025).
  - Use cases: Cardiac surgery, ECMO, hemorrhage management.
* ROTEM:
  - Used in neonatal sepsis (Sokou et al., 2024), coagulopathy (Erdoes et al., 2024), and ECMO (Cortesi et al., 2022).
  - Age-related reference ranges (Oswald et al., 2010).
  - Use cases: Infection-related coagulopathy, cardiac surgery.

Premature Infants: TEG/ROTEM have more data, with studies confirming balanced hemostasis in very low birthweight infants (Raffaeli et al., 2022). VCM's applicability is inferred but requires validation.

5.5 Comparison

6 Discussion

VCM's native blood approach simplifies neonatal testing, with studies confirming feasibility and reproducibility. TEG and ROTEM, using citrated blood,

Table 3: Viscoelastic Coagulation Monitors in Neonatology

Device	Sample Type	Volume	Applications	Limitations
VCM	Native	0.3 ml	NICU monitoring	Limited data, immediate testing
TEG	Citrated	0.36–1 ml	Cardiac, ECMO	Citrate processing
ROTEM	Citrated	0.36–1 ml	Sepsis, ECMO	Less portable

have more extensive data, particularly for premature infants. All devices outperform traditional tests (PT/aPTT) in capturing neonatal developmental hemostasis. VCM's lack of adverse events is promising, but its immediate testing requirement and limited premature infant data are challenges. Further research will enhance VCM's role in NICUs.

7 Conclusion

Research suggests VCM by Entegrion is effective for neonatal hemostatic monitoring, using minimal native blood for rapid, physiological assessment. TEG and ROTEM are more established, with broader applications in cardiac surgery, ECMO, and sepsis. For premature infants, balanced hemostasis supports viscoelastic testing, but VCM-specific data is sparse. The client can consider VCM for NICU use, ensuring standardized sampling, while leveraging TEG/ROTEM's extensive evidence base.

8 Recommendations

* Monitor the FDA MAUDE Database for VCM adverse events.
* Contact Entegrion, Inc. for neonatal guidelines.
* Implement standardized heel prick protocols for VCM reproducibility.
* Support trials for premature infant-specific VCM reference intervals.
* Download the report: Download PDF.

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