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By Electronic Submission

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852
Docket No. FDA 2013-S-0610

CITIZEN PETITION

Mosaic Clinical Technologies, Inc. ("Mosaic") submits this petition under 21 C.F.R. § 10.30 to request that the U.S. Food and Drug Administration ("FDA") take action to clarify the regulatory status of commercially available artificial intelligence ("AI") vision language models ("VLMs") that perform medical image analysis to support diagnosis and treatment and ensure consistent application of medical device requirements to these tools. The safety and effectiveness of these tools are of utmost importance to patient safety and ensuring clinically meaningful and reliable diagnostic outcomes for patients.

Mosaic, the technology services division of Radiology Partners ("RadPartners"), operates MosaicOS™—a fully cloud-native and AI-native operating system for radiologists. Mosaic believes diagnostic imaging VLMs represent an important and promising technological advancement with the potential to improve quality, efficiency, and access to patient care. This petition is not intended to discourage innovation, research, or responsible development of these technologies. Rather, it seeks regulatory clarity regarding the standards that should apply when such technologies are commercially distributed for clinical diagnostic use. As these technologies are increasingly commercialized and deployed in clinical settings, differing interpretations have emerged regarding the application of existing FDA medical device requirements, creating uncertainty for developers, healthcare organizations, clinicians, and patients. Clarity on standards will ultimately accelerate both the development and adoption of safe and trusted clinical diagnostic technologies. This petition seeks clarification regarding how existing statutory and regulatory principles should be applied consistently to commercially distributed diagnostic imaging VLMs and related technologies.

ACTIONS REQUESTED

Pursuant to Sections 201(h), 513, and 520(o) of the Federal Food, Drug, and Cosmetic Act ("FDCA"), and in accordance with FDA Good Guidance Practices, 21 CFR § 10.115, we respectfully request that FDA take the following actions:

- Clarify the regulatory principles used to determine when commercially distributed diagnostic VLMs constitute medical devices, including those intended for downstream adaptation or fine-tuning. Specifically, we request that FDA address whether a VLM marketed with the expectation of subsequent fine-tuning on institution-specific data is itself a medical device requiring premarket clearance or approval.

- Take other actions within its jurisdiction and authority to ensure consistent application of medical device requirements to commercially available VLMs intended for medical imaging or diagnosis.

STATEMENT OF GROUNDS

I. BACKGROUND

Recent years have seen the rise of a new paradigm of artificial intelligence ("AI") models termed *foundation models*. These models are ostensibly trained on large-scale datasets, across multiple modalities, can solve a variety of different downstream tasks, and can be easily adapted to new tasks or datasets.[1] Many capabilities of such foundation models function as regulated medical devices given their ability to identify abnormalities on medical images, such as cancer detection, breast density assessment, and other pathology identification. Despite the popularity of the term "foundation model" and the emergence of such models in academic literature and commercial marketing, there still exists no agreed-upon definition of a foundation model. More importantly, there is no agreed-upon definition of what the requisite performance, efficacy, benefits, and risks of such a foundation model should be.

Nonetheless, these foundation models are being explicitly designed, trained and marketed to perform diagnostic imaging analysis and other tasks and to support treatment and mitigation of disease. To reduce ambiguity in nomenclature around foundation models, we specifically refer to the class of generative VLMs that are being trained and marketed. Example VLMs include chest radiograph and mammography models intended to support medical diagnoses through the generation of text-based radiology reports. Such VLMs take as input one or more images or other clinical information and provide an output of unstructured text that typically describes the findings on the input medical images. These VLMs are then provided to third-party vendors and institutions, such as clinicians, healthcare facilities, picture archiving and communication system (PACS) or medical image management and processing system (MIMPS) vendors, and AI platform companies who fine-tune and deploy them locally, under varying interpretations of existing regulatory provisions, including the practice of medicine.

The growing prevalence and use of these models presents several questions regarding their safety, effectiveness, and performance in clinical settings. However, there is no established standard for verifying or validating the performance or quality of VLMs for clinical uses if they are not authorized by the FDA, both before and after the VLMs are fine-tuned prior to deployment. The absence of regulatory oversight and standardization significantly increases the risk that they may be trained on biased or unrepresentative datasets and that they lack transparency, explainability, and basic cybersecurity controls. All these risks have the potential to cause tangible patient harm.

In addition, several developers disclaim responsibility for the models' reliability or compliance with various legal requirements and provide few, if any, warranties or representations regarding the performance, reliability, or fitness of the models for the various diagnostic and clinical uses for which they are marketed. As a result, downstream users bear substantial responsibility for

[1] Paschali, M., Chen, Z., Blankemeier, L., Varma, M., Youssef, A., Bluethgen, C., ... & Chaudhari, A. (2025). Foundation models in radiology: what, how, why, and why not. *Radiology*, *314*(2), e240597.

determining whether these models are appropriate for their intended uses through their own quality, validation, and software engineering processes. Healthcare providers should maintain appropriate oversight and post-deployment monitoring of all AI models, including FDA-authorized devices. The concern, however, is that models introduced without premarket review may not have demonstrated the baseline safety and effectiveness required for FDA authorization and may not be subject to clearly defined total product lifecycle expectations for validation, change management, monitoring, and risk mitigation. Healthcare providers deploying these models, often with limited fine-tuning, may also lack the specialized AI expertise, monitoring infrastructure, and personnel needed to evaluate model performance adequately across the product lifecycle. Collectively, these factors increase the potential that clinically meaningful deficiencies, including those that might otherwise have precluded authorization, remain undetected until after deployment and contribute to misdiagnoses, false-positive findings, misinterpretations, and other adverse patient outcomes.

Stakeholders have adopted differing interpretations regarding whether and under what circumstances commercially distributed diagnostic imaging VLMs constitute medical devices under the FDCA. These differing interpretations appear to arise from varying views regarding the application of existing FDA medical device concepts to commercially distributed diagnostic imaging VLMs. In particular, stakeholders have reached different conclusions regarding: (1) the relevance of distinctions between components versus "finished devices," (2) when VLMs incorporated within general-purpose software-as-a-service ("SaaS") platforms are or are not medical devices requiring premarket approval, and (3) the scope of the statutory practice of medicine exemption. These differing interpretations have contributed to uncertainty regarding when existing medical device requirements apply and underscore the need for additional FDA clarification.

As discussed below, these developments raise important questions regarding how existing FDA concepts relating to intended use, components, finished devices, and clinical deployment should be applied to diagnostic imaging VLMs. While the use and availability of these models offer the potential to enhance the accuracy and speed of diagnosis, the widespread and largely unregulated use and integration of these VLMs into clinical practice poses numerous patient safety risks. As these models become more integral to diagnostic workflows, clarity on their regulatory status is critical.

II. FDA SHOULD CLARIFY WHEN DIAGNOSTIC IMAGING VLMs CONSTITUTE MEDICAL DEVICES

A. Intended Use Principles Support Classification of Certain Diagnostic Imaging VLMs as Medical Devices

VLMs that are specifically designed, trained, marketed, intended for use in the analysis of diagnostic medical images and capable of performing these functions upon commercialization are medical devices. The FDCA defines a medical device as "[a]n instrument. . . , including a component part, or accessory which is . . . (B) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals." The term "device" does not include certain stand-alone software functions excluded pursuant to

section 520(o).[2] However, section 520(o) of the FDCA does not exclude VLMs that are intended for use in diagnostic image analysis. In fact, FDA has interpreted the software exemptions in section 520(o) with respect to clinical decision support ("CDS") software to conclude that diagnostic image analysis is a device function.[3]

A product's "intended use" determines its regulatory status, the applicable product code and the general or special controls that may apply. FDA's regulation defines the intended use of a device as:

> the objective intent of the persons legally responsible for the labeling of an article (or their representatives). The intent may be shown by such persons' expressions, the design or composition of the article, or by the circumstances surrounding the distribution of the article. This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives. Objective intent may be shown, for example, by circumstances in which the article is, with the knowledge of such persons or their representatives, offered or used for a purpose for which it is neither labeled nor advertised; provided, however, that a firm would not be regarded as intending an unapproved new use for a device approved, cleared, granted marketing authorization, or exempted from premarket notification based solely on that firm's knowledge that such device was being prescribed or used by health care providers for such use. The intended uses of an article may change after it has been introduced into interstate commerce by its manufacturer. If, for example, a packer, distributor, or seller intends an article for different uses than those intended by the person from whom he or she received the article, such packer, distributor, or seller is required to supply adequate labeling in accordance with the new intended uses.[4]

The plain text of the FDCA and the intended use regulation support the conclusion that VLMs that are capable of analyzing clinical images for diagnostic purposes and are specifically designed, trained, marketed, and commercialized with this functionality and for this purpose are medical devices.

FDA has reinforced the notion that intended use, rather than platform, determines the medical device status of software. In its "Policy for Device Software Functions and Mobile Medical Applications Guidance for Industry and Food and Drug Administration Staff" (Sept. 2022) ("Software Policy"), the Agency stated that if a software function is intended for a medical device function, it is a medical device "regardless of the platform on which it is run," and FDA's oversight "is not determined by the platform."[5] Therefore, both the statute and FDA's historic interpretation of intended use provide a basis to regulate commercially available diagnostic imaging VLMs as medical devices.

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[2] 21 U.S.C. § 321(h).
[3] *See* U.S. Food and Drug Admin., "Clinical Decision Support Software: Guidance for Industry and Food and Drug Administration Staff" (Jan. 2026) *available at* https://www.fda.gov/media/109618/download.
[4] 21 C.F.R. § 801.4.
[5] U.S. Food and Drug Admin., "Policy for Device Software Functions and Mobile Medical Applications Guidance for Industry and Food and Drug Administration Staff" (Sept. 2022) at 6, *available at* https://www.fda.gov/media/80958/download.

B. Diagnostic Imaging VLMs Are Not Merely Components of Finished Devices

Many VLMs are marketed as components of downstream finished device software devices or systems. However, VLMs that are specifically designed, trained, and intended for use in diagnostic image analysis go beyond the function and definition of traditional medical device components.[6]

A key distinction between components and finished devices is whether the item is suitable for use or capable of functioning upon deployment or distribution. FDA defines a component as "any raw material, substance, piece, part, software, firmware, labeling, or assembly that is intended to be included as part of the finished, packaged, and labeled device."[7] A finished device is "any device or accessory to any device that is *suitable for use or capable of functioning, whether or not it is packaged, labeled, or sterilized*."[8] The regulatory framework assumes that components are not capable of executing the core device function on their own and are not capable of performing those functions without further assembly, manufacturing or fine-tuning within the finished device platform. This distinction is the basis for exempting components from requirements and controls that apply to finished devices.

In the case of the many diagnostic imaging VLMs being commercialized to end users, they are capable of performing diagnostic functions without fine-tuning or further manipulation by the end user. In fact, the mere terminology of fine-tuning of AI models implies that the base model being fine-tuned has some baseline capabilities to perform the task in question. The act of fine tuning is simply to boost that performance and/or make the model more robust. This notion further reinforces the fact that such models being fine-tuned are far closer to being a "finished device," rather than a "component."

Some developers provide not only diagnostic imaging VLMs, but also infrastructure, development environments, implementation support, and other resources intended to facilitate adaption, validation, deployment, and ongoing use of those models in clinical settings. However, in many cases, very little if any further fine-tuning is required to deploy models for clinical diagnosis. Moreover, the very definition of fine-tuning is challenging to objectively define. If a VLM has 100 million parameters (weights), does changing a single parameter by 1% constitute that the final model has been fine-tuned? The increasing availability of fine-tuning approaches highlights the need for FDA clarification regarding the circumstances under which downstream adaptation materially changes the regulatory status of a commercially distributed model.

Further, clarity is needed regarding the relevance of prior FDA guidance related to general-purpose SaaS platforms and third-party AI VLMs to whether commercially available diagnostic imaging VLMs are medical devices if they have an intended use that puts them within the statutory definition. FDA has long recognized that off-the-shelf ("OTS") software and general-purpose SaaS platforms are routinely incorporated into medical devices or used to help execute certain medical

[6] Components and parts are exempt from FDA's Quality Management System Regulation (QMSR) and, by extension, most medical device requirements. *See* 21 C.F.R. § 820.1(a)(2).
[7] 21 C.F.R. § 820.3(a).
[8] [8] 21 C.F.R. § 820.3(a).

device functions. FDA does not necessarily regulate these tools as medical devices.[9] Rather, the Agency expects the finished device manufacturer to ensure that these software solutions are integrated or used in a manner that ensures the continued safe and effective performance of the medical device.

FDA has also acknowledged that third-party AI VLMs may be integrated into finished devices, but it has expressed the need for a comprehensive approach for the use of such models "due to the opacity of many models and model reliance on data correlations that may not map directly to biologically plausible mechanisms of action."[10] In its "Artificial Intelligence-Enabled Device Software Functions: Lifecycle Management and Marketing Submission Recommendations: Draft Guidance for Industry and Food and Drug Administration Staff" (Jan. 7, 2025), the Agency provided recommendations for manufacturers of AI-enabled devices to ensure that third-party VLMs are fit for purpose and perform as expected. However, the Agency did not expressly address the regulatory status of such VLMs. Importantly, the Agency did not classify such models as components or define the circumstances in which such models may meet the definition of finished devices. While many of the comments on the draft guidance encourage FDA to exempt VLMs from medical device requirements, a categorical exemption of VLMs is not consistent with the statutory framework. Therefore, current FDA guidance is unclear, making it necessary for the FDA to provide further guidance for industry participants--suppliers and customers alike.

C. The Practice of Medicine Is Narrow and Should Not be Interpreted to Permit Unregulated Commercialization of Diagnostic VLMs

We do not believe FDA should eliminate the practice of medicine as an important tool to support innovation by providers to improve care delivery. In the specific category of VLMs, it is important for FDA to clarify the boundaries and standards for any technology product that can be marketed and licensed to providers for that purpose. Mosaic supports the continued availability of the practice of medicine as an important mechanism that enables healthcare providers to innovate and improve patient care. The purpose of this petition is to clarify the circumstances under which commercially distributed diagnostic imaging VLMs should be regulated prior to their acquisition and use by healthcare organizations. Mosaic understands that the practice of medicine does not excuse developers from FDA oversight when they commercialize and market VLMs to healthcare providers that are capable of performing clinical image diagnostic functions at the time of distribution and seeks confirmation from the FDA on this point.

FDA does not regulate the practice of medicine, i.e., how licensed health care professionals ("HCPs") diagnose, treat, or care for their patients, and HCPs may prescribe or use FDA-approved devices for unapproved, or "off-label," indications.[11] In addition, FDA regulations exempt certain

[9] *See* Off-the-Shelf Software Use in Medical Devices: Guidance for Industry and Food and Drug Administration Staff (2023), available at https://www.fda.gov/media/71794/download.
[10] U.S. Food and Drug Admin., "Artificial Intelligence-Enabled Device Software Functions: Lifecycle Management and Marketing Submission Recommendations: Draft Guidance for Industry and Food and Drug Administration Staff" (Jan. 7, 2025) at 5, *available at* https://www.fda.gov/media/184856/download.
[11] *See* 21 U.S.C. § 396.

devices from premarket notification requirements, including a device that "is intended solely for use by a physician or dentist (or other specially qualified person) and is not generally available to, or generally used by, other physicians or dentists (or other specially qualified persons)."[12] Taken together, these provisions have been interpreted to allow HCPs to use custom devices or modify legally marketed devices for limited use within the scope of the HCP's practice outside of general commercial distribution or use.

While this interpretation reflects a historical Congressional intent to respect and protect HCPs' discretion to make treatment decisions within the bounds of a practitioner-patient relationship, it does not permit the unauthorized distribution and sale of medical devices for commercial purposes, and it does not shield a manufacturer who commercially distributes an unapproved device. In fact, the FDCA makes clear that the practice of medicine exemption does not "change any existing prohibition on the promotion of unapproved uses of legally marketed devices."[13] By extension this provision does not change existing prohibitions on the commercialization and marketing of unapproved medical devices.

In the case of many diagnostic imaging VLMs, developers argue that because healthcare providers are fine-tuning and deploying these models locally, FDA cannot intervene once the model is adapted within a clinical setting. However, the practice of medicine exemption applies only to the clinical practice of practitioners, and it does not exempt manufacturers from obtaining clearance or approval for a product they commercially distribute. Moreover, marketing VLMs with the specific knowledge and intent that they will be used for clinical diagnosis with little to no alteration or fine tuning demonstrates an express medical device intended use. This growing trend requires clarification from the FDA. Specifically, FDA should clarify the parameters that make a foundation AI model (or VLM) cross over into the domain of a medical device and therefore make that AI model (or VLM) subject to regulatory oversight prior to commercialization to a provider for any purpose; including fine-tuning or further development under a medical use exemption.

D. The Unregulated Commercialization of Diagnostic VLMs Presents Significant Patient Safety and Quality Risks

The commercialization of diagnostic VLMs without appropriate FDA oversight introduces significant risks to patient safety and quality of care. These models may be deployed without a clear understanding of their safety, limitations, or real-world performance. Examples illustrate commercially available deployment approaches that have contributed to differing interpretations regarding the application of existing medical device requirements to diagnostic imaging VLMs. For example, some commercially marketed VLM platforms promote the use of foundation models capable of supporting diagnostic tasks and claim that fine-tuning is essential to achieving "radiologist-level accuracy and consistency." Other platforms market the ability to adapt VLMs to "specific use case, patient population, and imaging context" through end-user fine-tuning functions.

[12] 21 C.F.R. § 807.85
[13] 21 U.S.C. § 396.

The increasing availability of these capabilities highlights the need for regulatory clarity regarding validation, performance assessment, transparency, and the respective responsibilities of developers, distributors, healthcare organizations, and other stakeholders involved in the deployment of diagnostic imaging VLMs. Regulatory clarity is important because diagnostic performance depends not only on model architecture, but also on the quality and repetitiveness of training data, validation methodology, deployment environment, and ongoing performance monitoring. Consistent expectations regarding validation, transparency, post-deployment monitoring, and quality management would improve confidence that clinically deployed diagnostic VLMs perform reliably across diverse patient populations and practice settings. These principles are already foundations to the FDA's medical device framework and provide an established approach for managing the evolving AI-enabled technologies throughout their lifecycle. Without standardized validation and transparency into training data and performance, models may be trained on incomplete, biased, or unrepresentative datasets. As a result, models may not perform reliably across diverse populations, settings, and clinically relevant patient subgroups.

Accordingly, diagnostic VLMs that are distributed commercially without the safeguards associated with FDA authorization can create a pathway for clinically meaningful errors, including misdiagnoses, false positives, and misinterpretations. For healthcare providers, the absence of regulatory oversight and clear standards shifts risk into the clinical setting, placing responsibility on clinicians to identify model limitations and manage potential errors. Healthcare organizations bear responsibility for locally validating, monitoring, and managing AI systems deployed within their clinical environments. However, those activities have traditionally occurred in conjunction with products whose underlying intended use and baseline performance have already been evaluated through an established regulatory framework. Where diagnostic imaging VLMs are commercially distributed without prior FDA review of the underlying diagnostic capability, uncertainty may arise regarding validation expectations, quality management responsibilities, and the consistent application of established medical device standards across the clinical ecosystem.

It is our understanding that fine-tuning can indeed improve the performance of VLMs, such as by adapting models to site-specific data and patient populations. However, existing regulatory pathways for fine-tuning assume that the underlying system has already been reviewed and authorized as a medical device through appropriate premarket review (e.g., FDA clearance or Premarket Approval (PMA)). Where VLMs are deployed and fine-tuned without this baseline regulatory framework, there are no consistent expectations for validation, reproducibility, transparency, quality management, or lifecycle performance monitoring. Existing FDA frameworks for managing post-market modifications, such as predetermined change control plans (PCCPs), demonstrate that the Agency already has an appropriate framework for managing the adaptation of AI-enabled medical devices after an initial determination that the underlying system is safe and effective.

E. Diagnostic Imaging VLMs Are Distinguishable from Laboratory-Developed Tests

Some developers may analogize locally fine-tuned VLMs to laboratory-developed tests ("LDTs"). This analogy does not apply to VLM devices for two reasons, enumerated below.

First, the LDT decision rested on the conclusion that a laboratory-developed test is a professional service performed within a single laboratory and does not meet the statutory definition of a "device." Software occupies a different statutory position. Through the 21st Century Cures Act, Congress expressly addressed software functions within the device framework, excluding only enumerated low-risk categories and preserving device status for software intended to analyze medical images for diagnostic purposes. The reasoning that removed LDTs from the device definition therefore has no application to diagnostic imaging VLMs, which fall squarely within the statutory text Congress enacted.

Second, the LDT analysis is rooted in a test that is designed, manufactured, and used within a single laboratory, without commercial distribution. Diagnostic imaging VLMs, by contrast, are developed by a manufacturer and commercially distributed to numerous third-party sites while engaging in interstate commerce. Site-specific fine-tuning does not transform a commercially distributed product into an in-house service, particularly where the diagnostic capability is present in the base model prior to distribution, as described in Section II.A and II.B above.

III. LEGAL BASIS FOR REQUESTED ACTION

The Agency interprets medical device requirements under the FDCA through regulations or guidance.[14] Such interpretations are not only appropriate where the FDCA is silent on an issue, but where clarity is necessary to advance public health, ensure consistent application and enforcement of the law, and avoid arbitrary outcomes that are inconsistent with the letter and spirit of the law.

This petition does not seek to restrict academic research, clinical investigation, algorithm development, evidence generation, or responsible innovation. Research activities conducted under appropriate institutional review board ("IRB") oversight and intended to generate evidence regarding safety, effectiveness, or for future FDA review serve an important public health function. The focus of this petition is limited to the commercialization and clinical deployment of diagnostic VLMs where questions remain regarding the application of existing medical device requirements.

We are concerned that conflicting interpretations of regulatory requirements can create inconsistent compliance. Where developers assert that diagnostic capability is not present prior to distribution because a model will undergo downstream fine-tuning, questions may nevertheless remain regarding the extent to which the base model provides the primary diagnostic functionality prior to such adaptation. The extent to which downstream fine-tuning changes the regulatory status of a commercially distributed model remains an important area in which additional FDA clarification would be valuable.

[14] *See* 5 U.S.C. §§ 551-559.

FDA should clarify the respective responsibilities of developers, distributors, healthcare organizations, and other stakeholders involved in the deployment of diagnostic VLMs. Clear expectations regarding validation, performance monitoring, transparency, and quality management would support patient safety, promote responsible innovation, and provide greater consistency across the healthcare ecosystem.

Given the rapid expansion of VLM commercialization in medical imaging and the differences in regulatory interpretation of current FDA definitions, we respectfully request that the FDA provide clear guidance on the regulatory status of VLMs used in medical imaging, specifically by providing clarification on when a VLM constitutes a medical device (e.g., how intended use should be assessed for VLMs marketed for downstream diagnostic applications). We also request that FDA provide guidance regarding the responsibilities of developers, distributors, healthcare organizations, and other stakeholders involved in the deployment of diagnostic VLMs.

Different stakeholders have reached differing conclusions regarding how existing medical device concepts, including intended use, device components, finished devices, and clinical deployment, apply to diagnostic imaging VLMs. Because these differing interpretations affect technologies that may influence patient diagnosis and treatment, FDA clarification would benefit patients, clinicians, researchers, developers, healthcare organizations, and regulators.

IV. CONCLUSION

For the aforementioned reasons, we respectfully request that FDA grant the actions requested in this petition. Clarification from the Agency would benefit patients, healthcare providers, developers, healthcare organizations, researchers, and other stakeholders by promoting consistent interpretation of existing medical device requirements while continuing to support responsible innovation. We appreciate the FDA's leadership in protecting public health and supporting safe innovation in medical imaging and AI.

ENVIRONMENTAL IMPACT

The actions requested in this petition are subject to categorical exclusion under 21 C.F.R. § 25.34.

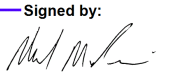
ECONOMIC IMPACT

Information on the economic impact of this proposal will be submitted upon request of the Commissioner.

CERTIFICATION UNDER 21 CFR § 10.30

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Sincerely,

Signed by:

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