### Summary of Relevant FDA Summary PDF Files for Stroke Analysis/Package:

#### \*\*K180647\*\*

- \*\*Device Name\*\*: BriefCase

- \*\*Intended Use\*\*: Radiological computer-aided triage and notification software for the analysis of non-enhanced head CT images. Specifically indicated for the detection of Intracranial Hemorrhage (ICH).

- \*\*Description\*\*: Uses an AI algorithm to analyze images and highlight cases with suspected ICH, providing notifications and compressed preview images for informational purposes. Not intended for diagnostic use beyond notification.

- \*\*Performance\*\*: Sensitivity of 93.6% and specificity of 92.3%. Documented a significant reduction in time-to-notification compared to standard time-to-exam-open, enhancing workflow prioritization.

#### \*\*K190072\*\*

- \*\*Device Name\*\*: BriefCase

- \*\*Intended Use\*\*: Radiological computer-aided triage and notification software for the analysis of non-enhanced head CT images, detecting Intracranial Hemorrhage (ICH).

- \*\*Description\*\*: Similar to K180647, uses AI to analyze and flag suspected ICH cases, facilitating faster triage and prioritization.

- \*\*Performance\*\*: Emphasizes substantial equivalence to legally marketed devices, enhancing radiologist workflow and decision-making processes through timely notifications.

#### \*\*K190896\*\*

- \*\*Device Name\*\*: BriefCase

- \*\*Intended Use\*\*: Analysis of non-enhanced head CT images for Intracranial Hemorrhage (ICH) detection.

- \*\*Description\*\*: AI-driven analysis, providing workflow triage support by highlighting suspected ICH cases and offering compressed preview images.

- \*\*Performance\*\*: Consistent with other BriefCase devices, focusing on improving radiologist response times and decision accuracy.

#### \*\*K192383\*\*

- \*\*Device Name\*\*: BriefCase

- \*\*Intended Use\*\*: Analysis of head and neck CTA images, relevant for Large Vessel Occlusion (LVO) detection, which is critical in stroke diagnosis and management.

- \*\*Description\*\*: AI-based software that identifies and flags LVO, enhancing triage and communication among medical staff.

- \*\*Performance\*\*: Validated through a study demonstrating its efficacy in accurately identifying LVOs, supporting expedited clinical decision-making.

#### \*\*K220709\*\*

- \*\*Device Name\*\*: BriefCase

- \*\*Intended Use\*\*: Analysis of head CTA images in adults to detect both complete Large Vessel Occlusions (LVO) and Medium Vessel Occlusions (MeVO).

- \*\*Description\*\*: Utilizes AI to identify and notify clinicians of potential occlusions, providing compressed preview images for triage purposes.

- \*\*Performance\*\*: Aimed at improving the accuracy and speed of LVO and MeVO detection, thus aiding in the prompt management of stroke patients.

#### \*\*K221314\*\*

- \*\*Device Name\*\*: BriefCase

- \*\*Intended Use\*\*: LVO triage in head CTA images.

- \*\*Description\*\*: AI-driven tool designed to flag and prioritize cases with suspected LVO, supporting rapid intervention and treatment decisions.

- \*\*Performance\*\*: Demonstrated substantial equivalence to predicate devices, with enhanced capabilities for identifying LVO and facilitating timely clinical responses.

### Conclusion:

The above summaries highlight the relevant details from the selected FDA summaries, focusing on their application in stroke analysis and management. These devices utilize AI algorithms to aid in the detection and triage of critical stroke-related conditions such as Intracranial Hemorrhage (ICH) and Large Vessel Occlusion (LVO), significantly enhancing the efficiency and accuracy of clinical workflows.

### 中风分析/包的相关 FDA 摘要 PDF 文件摘要：

#### \*\*K180647\*\*

- \*\*设备名称\*\*：BriefCase

- \*\*预期用途\*\*：用于分析非增强头部 CT 图像的放射计算机辅助分类和通知软件。专门用于检测颅内出血 (ICH)。

- \*\*描述\*\*：使用 AI 算法分析图像并突出显示疑似 ICH 的病例，提供通知和压缩预览图像以供参考。除通知外，不用于诊断用途。

- \*\*性能\*\*：灵敏度为 93.6%，特异性为 92.3%。与标准检查打开时间相比，记录到通知时间显著减少，增强了工作流程优先级。

#### \*\*K190072\*\*

- \*\*设备名称\*\*：BriefCase

- \*\*预期用途\*\*：用于分析非增强头部 CT 图像的放射计算机辅助分类和通知软件，用于检测颅内出血 (ICH)。

- \*\*描述\*\*：与 K180647 类似，使用 AI 分析和标记疑似 ICH 病例，促进更快的分类和优先级排序。

- \*\*性能\*\*：强调与合法销售设备的实质等同性，通过及时通知增强放射科医生的工作流程和决策过程。

#### \*\*K190896\*\*

- \*\*设备名称\*\*：BriefCase

- \*\*预期用途\*\*：分析非增强头部 CT 图像以检测颅内出血 (ICH)。

- \*\*描述\*\*：AI 驱动的分析，通过突出显示疑似 ICH 病例并提供压缩预览图像来提供工作流程分类支持。

- \*\*性能\*\*：与其他 BriefCase 设备一致，专注于提高放射科医生的响应时间和决策准确性。

#### \*\*K192383\*\*

- \*\*设备名称\*\*：BriefCase

- \*\*预期用途\*\*：分析头部和颈部 CTA 图像，与大血管闭塞 (LVO) 检测相关，这对中风诊断和管理至关重要。

- \*\*描述\*\*：基于 AI 的软件，可识别和标记 LVO，增强医务人员之间的分类和沟通。

- \*\*性能\*\*：通过一项研究验证，证明其在准确识别 LVO 方面的功效，支持加快临床决策。

#### \*\*K220709\*\*

- \*\*设备名称\*\*：BriefCase

- \*\*预期用途\*\*：分析成人头部 CTA 图像，以检测完全大血管闭塞 (LVO) 和中血管闭塞 (MeVO)。

- \*\*描述\*\*：利用 AI 识别并通知临床医生潜在的阻塞，提供压缩预览图像以供分类。

- \*\*性能\*\*：旨在提高 LVO 和 MeVO 检测的准确性和速度，从而帮助及时管理中风患者。

#### \*\*K221314\*\*

- \*\*设备名称\*\*：BriefCase

- \*\*预期用途\*\*：头部 CTA 图像中的 LVO 分类。

- \*\*描述\*\*：AI 驱动的工具，旨在标记和优先处理疑似 LVO 的病例，支持快速干预和治疗决策。

- \*\*性能\*\*：证明与谓词设备具有实质等效性，具有增强的识别 LVO 和促进及时临床反应的能力。

### 结论：

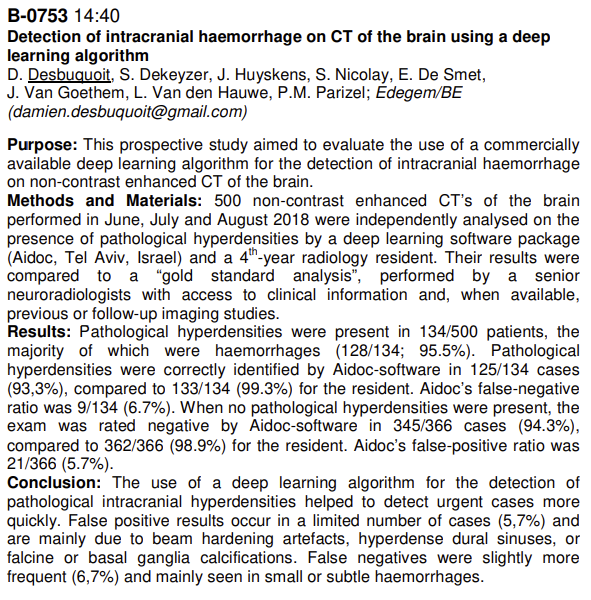
以上摘要重点介绍了所选 FDA 摘要中的相关细节，重点介绍了它们在中风分析和管理中的应用。这些设备利用人工智能算法来辅助检测和分类与中风相关的严重疾病，例如颅内出血 (ICH) 和大血管闭塞 (LVO)，从而显著提高临床工作流程的效率和准确性。

The ECR 2019 Book of Abstracts is published by the European Society of Radiology (ESR) and summarises the presentations accepted to be held at the European Congress of Radiology 2019 (Vienna, Austria, February 27 - March 3, 2019).

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ECR 2019 摘要集由欧洲放射学会 (ESR) 出版，总结了 2019 年欧洲放射学会大会 (2019 年 2 月 27 日至 3 月 3 日，奥地利维也纳) 上接受的演讲。

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使用深度学习算法在脑 CT 上检测颅内出血

目的：这项前瞻性研究旨在评估使用市售的深度学习算法在非造影增强脑 CT 上检测颅内出血

的方法。

方法和材料：使用深度学习软件包（Aidoc，以色列特拉维夫）和一名四年级放射科住院医师对 2018 年 6 月、7 月和 8 月进行的 500 次非造影增强脑 CT 进行独立分析，以确定是否存在病理性高密度。他们的结果与“黄金标准分析”进行了比较，该分析由一位资深神经放射学家执行，该分析具有临床信息，并且如果可用，还可以进行先前或后续的影像学研究。

结果：500 名患者中有 134 名出现病理性高密度，其中大多数是出血（128/134；95.5%）。Aidoc 软件在 134 例中正确识别了 125 例病理性高密度（93.3%），而住院医生的正确识别率为 134 例中的 133 例（99.3%）。Aidoc 的假阴性率为 134 例中的 9 例（6.7%）。当不存在病理性高密度时，Aidoc 软件将 345/366 例 (94.3%) 的检查结果评为阴性，而住院医生的评为 362/366 (98.9%)。Aidoc 的假阳性率为 21/366 (5.7%)。

结论：使用深度学习算法检测病理性颅内高密度有助于更快地发现紧急情况。假阳性结果出现在有限数量的病例中 (5.7%)，主要是由于光束硬化伪影、高密度硬脑膜窦或镰状细胞或基底神经节钙化。假阴性出现的频率略高 (6.7%)，主要见于小出血或细微出血。

Aidoc's BriefCase, including the stroke package, has achieved significant regulatory approvals that go beyond the FDA. Here are the key certifications:

1. \*\*FDA Approval\*\*:

- Aidoc's stroke package, which includes modules for detecting intracranial hemorrhage (ICH) and large vessel occlusion (LVO), has received multiple FDA clearances. This approval ensures the AI solution meets stringent safety and efficacy standards for use in the United States.

2. \*\*CE Mark Certification\*\*:

- Aidoc's stroke package is also CE-marked, which signifies conformity with health, safety, and environmental protection standards for products sold within the European Economic Area (EEA). This approval is crucial for market access in Europe and indicates the product meets high-quality and safety standards required by the European Medicines Agency (EMA)【142†source】【143†source】.

3. \*\*ISO 13485:2016 Certification\*\*:

- Aidoc holds an ISO 13485:2016 certification, which is an internationally recognized standard for quality management systems specific to medical devices. This certification ensures that Aidoc's products meet regulatory requirements consistently and are manufactured under a robust quality management system【145†source】.

While specific mentions of the Therapeutic Goods Administration (TGA) approval for the stroke package were not found, Aidoc’s general compliance with international quality standards and certifications suggests it is well-regarded globally and may likely adhere to TGA standards as well.

These regulatory approvals and certifications underline the reliability and safety of Aidoc’s AI solutions in multiple regions, making them a trusted choice for medical professionals in enhancing stroke diagnosis and management.

 **K192383** - This document contains information about the stroke protocol assessment and head and neck CTA, which is relevant for large vessel occlusion (LVO) detection and stroke analysis.

 **K220709** - This document discusses the Aidoc BriefCase for head CTA images, focusing on identifying vessel occlusion (VO), which is pertinent to stroke cases.

 **K201020** - This document covers the BriefCase for incidental pulmonary embolism (iPE) triage but mentions head CT and CTPA protocols, potentially overlapping with stroke analysis tools.

 **K213721** - This document relates to the Aidoc BriefCase for brain aneurysm (BA) triage, which can be associated with stroke risk and analysis.

 **K221314** - This document provides information on the BriefCase for LVO triage, directly relevant to stroke detection and management.

K180647: Focuses on Aidoc's BriefCase for radiological computer-aided triage and notification software, specifically for analyzing non-enhanced head CT images to detect Intracranial Hemorrhage (ICH). This is directly related to stroke analysis.

K190072: Details the use of Aidoc's BriefCase for analyzing non-enhanced head CT and CTPA images, including Intracranial Hemorrhage (ICH) detection. This is relevant for stroke analysis as ICH is a common type of stroke.

K190896: Discusses Aidoc's BriefCase, including its application for head CT images to assist in the detection of Intracranial Hemorrhage (ICH), which is relevant for stroke analysis.

K192383: Contains information about the stroke protocol assessment and head and neck CTA, which is relevant for large vessel occlusion (LVO) detection and stroke analysis.

K221314:Provides details on the BriefCase for LVO triage, directly relevant to stroke detection and management.

K220709:

Discusses the Aidoc BriefCase for head CTA images, focusing on identifying vessel occlusion (VO), pertinent to stroke cases.