

**K200898 Medicon Hellas Albumin, Medicon Hellas Calcium,
Medicon Hellas Creatinine, Medicon Hellas Urea Nitrogen,
Medicon Hellas Glucose, Medicon Hellas Total Bilirubin,
Medicon Hellas Direct Bilirubin**Sep 21, 2021
536 days to decisionK200898 · Product code: **CIX** · Chemistry
Source: <https://www.510kdatabase.net/k200898/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Bromocresol Green Dye-binding, Albumin (CIX) |
| Date received | Apr 3, 2020 |
| Decision date | Sep 21, 2021 |
| Days to decision | 536 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Medicon Hellas S.A |
| Location | Gerakas, Attiki, GR |
| Contact | Frank Matuszak |
| 510(k) history | 3 submissions · 3 cleared · 2006-2024 |

REGULATORY CONSULTANT

| | |
|-----------------|---------------------------------------|
| Consulting firm | Ammirati Regulatory Consulting |
| Contact | Sotia Mitropoulou |

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k200898/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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