

K 964609

MAR - 6 1997

9. 510(k) Summary of Information Respecting Safety and Effectiveness

A. Legally Marketed Device

Array Medical claims substantial equivalence to the HEMOCHRON Whole Blood Coagulation System and Activated Clotting Time Tests (pre-1976), currently in commercial distribution by International Technidyne Corporation.

B. Device Description

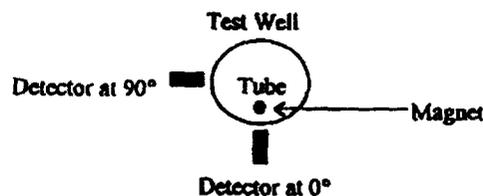
Actalyke System

The Actalyke System is a portable, battery operated device designed to perform a range of whole blood coagulation tests at the patient's bedside using Activated Clotting Time (ACT) measurement techniques.

ACT Measurement Principles

A step-by-step description of the Actalyke ACT measurement principle is provided below:

- 1) Each test well of the Actalyke Instrument incorporates a highly sensitive clot detection mechanism.
- 2) Operationally, the detection mechanism comprises a magnet located inside a test tube and two solid state magnetic detectors positioned within the test well - one situated at 0° and another situated at 90° with respect to the test tube. See below:



- 3) When a test tube is inserted into the test well, the detector at 0° senses the presence of the magnet as the tube slowly rotates.
- 4) As clotting forms, the fibrin strands cause the magnet to rotate within the tube such that its presence is sensed by the detector at 90° (indicating the occurrence of clotting and triggering end-point detection). This two-point detection sensing system is an improvement in ACT detection methods and minimizes the possibility of a missed end-point.

Device Description (continued)

Actalyke Activated Clotting Time Tubes

Each Actalyke test tube has a barcode label affixed to it, which is read by the Actalyke instrument to determine the test tube type (i.e., celite, kaolin, or glass bead). If the result is printed (optional), the normal range for the identified test tube type will be printed. The lot number and expiration date of each tube are also identified on the barcode label.

<u>Cat. No.</u>	<u>Recomm. Use</u>	<u>Activator</u>	<u>Description</u>
C-ACT	Bypass and Vascular surgery	Celite (14 mg.)	Glass tube with black flip-top tube and barcode label. 2.0 ml blood sample
K-ACT	Bypass surgery in the presence aprotinin	Kaolin (14 mg.)	Glass tube with gold flip-top and barcode label. 2.0 ml blood sample
G-ACT	Renal Dialysis	Glass beads (50 mg.)	Plastic tube with clear flip-top and barcode label. 0.4 ml blood sample

NOTE: Used Actalyke test tubes should be disposed of in accordance with each institution's policy regarding biohazardous materials.

C. Intended Use

The Actalyke Activated Clotting Time System and Test Tubes are intended for use in the measurement of the activated clotting time test (ACT). Current markets using the ACT include: bypass surgery, vascular surgery, transplant surgery, renal dialysis, ECMO, cardiac catheterization and Percutaneous Transluminal Coronary Angioplasty (PTCA), Critical Care, and other medical therapies requiring heparin anticoagulation.

D. Comparison with Predicate Device

Feature Comparison of Actalyke and HEMOCHRON Systems

	Actalyke	HEMOCHRON
Intended Use	Activated Clotting Time Test	Activated Clotting Time Test
Method of detection	Magnetic detection	Magnetic Detection
Reactive Ingredients (tubes)	Celite, kaolin, glass-beads	Celite, kaolin, glass-beads
Storage of tubes	Room temperature	Room temperature
Materials provided	Instrument Test Tubes Controls	Instrument Test Tubes Controls
Instrument Specifications	<ul style="list-style-type: none"> • No. Test Channels: 1 or 2 • Timing Range: 0-1500 • Operating Time on Battery (hours): 4-6 • Test barcode identification • Options: Printer 	<ul style="list-style-type: none"> • No. Test Channels: 1 or 2 • Timing Range: 0-1500 • Operating Time on Battery (hours): 4-6
Performance	C-ACT 105-130 sec. K-ACT 114-130 sec. G-ACT 165-212 sec. Normal Range studies	CA510 105-167 sec. K-ACT 91-151 sec. P214 145-195 sec. Normal Range studies

E. Performance Data
Specific Performance Characteristics
 Normal Range Study

Celite Normal Range Study

Instrument Tubes		Hemochron		Actalyke	
No	Patient ID	Hemochron	Actalyke	Hemochron	Actalyke
1	S011	129	133	103	117
2	S012	124	126	118	125
3	S013	112	118	106	113
4	S014	110	110	100	109
5	S015	104	112	113	125
6	S016	109	114	108	117
7	S002	108	117	109	112
8	S017	116	119	112	123
9	S018	107	114	112	117
10	S019	101	108	100	110
11	S020	109	115	110	116
12	S021	121	129	120	130
13	S022	104	106	102	112
14	S023	113	124	110	122
15	S024	108	112	110	115
mean		111.87	117.13	108.87	117.53
std		7.83	7.83	5.95	6.20
%cv		7.01	6.68	5.47	5.27
max		129.00	133.00	120.00	130.00
min		101.00	106.00	100.00	109.00
x-2std		96.02	101.48	96.97	105.14
x+2std		127.32	132.79	120.77	129.93
x-3std		88.19	93.85	91.01	98.94
x+3std		135.14	140.62	128.72	136.13

Kaolin Normal Range Study

Instrument Tubes		Hemochron		Actalyke	
No	Patient ID	Hemochron	Actalyke	Hemochron	Actalyke
1	S033	118	128	107	117
2	S034	118	119	108	118
3	S035	116	120	105	119
4	S036	122	128	115	125
5	S037	114	122	110	119
6	S004	116	125	118	128
7	HL001	119	130	115	122
8	S005	122	132	119	128
9	S037	108	118	108	121
10	S038	112	121	114	120
11	S009	122	133	122	127
12	S030	119	127	121	126
13	S031	115	121	116	122
14	S039	110	125	106	118
15	S040	109	119	108	119
mean		116.00	124.53	112.80	121.93
std		4.66	4.96	5.71	3.88
%cv		4.02	3.98	5.06	3.18
max		122.00	133.00	122.00	128.00
min		108.00	118.00	105.00	117.00
x-2std		106.68	114.62	101.38	114.17
x+2std		125.32	134.44	124.22	129.70
x-3std		102.02	109.67	95.67	110.29
x+3std		129.98	139.40	129.93	133.58

Glass Bead Normal Range Study

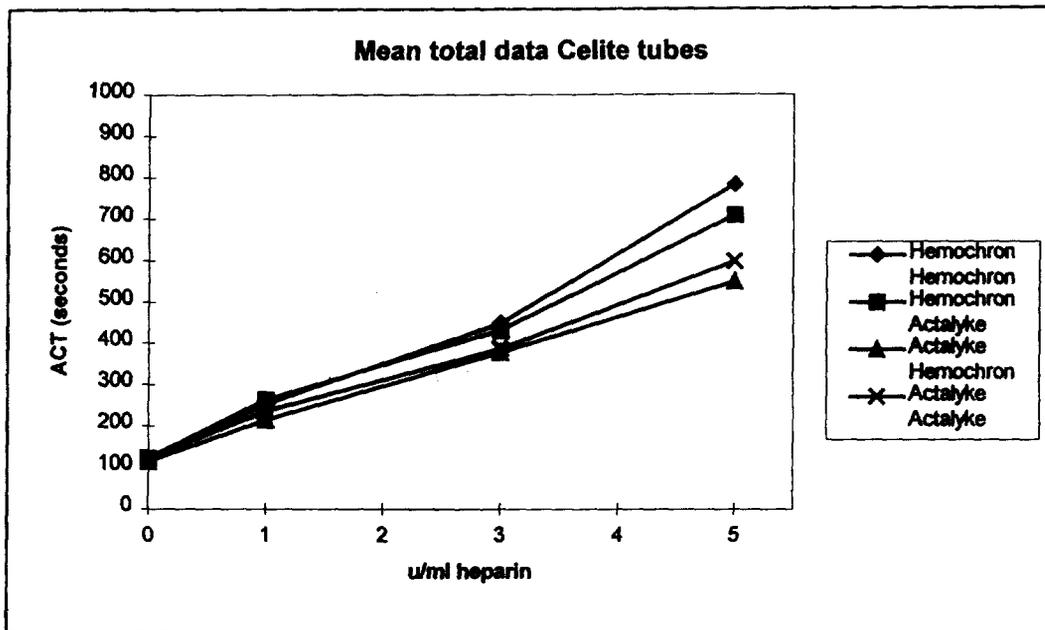
Instrument Tubes		Hemochron		Actalyke	
No	Patient ID	Hemochron	Actalyke	Hemochron	Actalyke
1	S051	188	180	188	203
2	S027	175	168	163	185
3	S025	177	167	177	199
4	S052	178	199	199	198
5	S028	166	169	178	178
6	S019	162	167	163	167
7	S035	168	197	158	199
8	S045	173	172	179	172
9	ITL001	171	190	155	189
10	S049	191	186	157	203
11	S048	174	169	181	197
12	S006	169	180	185	185
13	S016	157	176	166	177
14	S030	150	178	167	183
15	S009	145	179	170	188
	mean	169.60	178.47	172.40	188.20
	std	12.55	10.56	12.76	11.45
	%cv	7.40	5.91	7.40	6.08
	max	191.00	199.00	199.00	203.00
	min	145.00	167.00	155.00	167.00
	x-2std	144.50	157.35	146.88	165.31
	x+2std	194.70	199.58	197.92	211.09
	x-3std	131.95	146.80	134.12	153.66
	x+3std	207.25	210.13	210.68	222.54

Correlation with predicate device

Summary Celite tubes

Mean data u/ml heparin

Instrument	tube	0	1	3	5
Hemochron	Hemochron	120.6	252.4	448.8	782.2
Hemochron	Actalyke	123	264	431.8	709.2
Actalyke	Hemochron	114	214.2	377.4	548
Actalyke	Actalyke	122	235.2	386.8	598.6

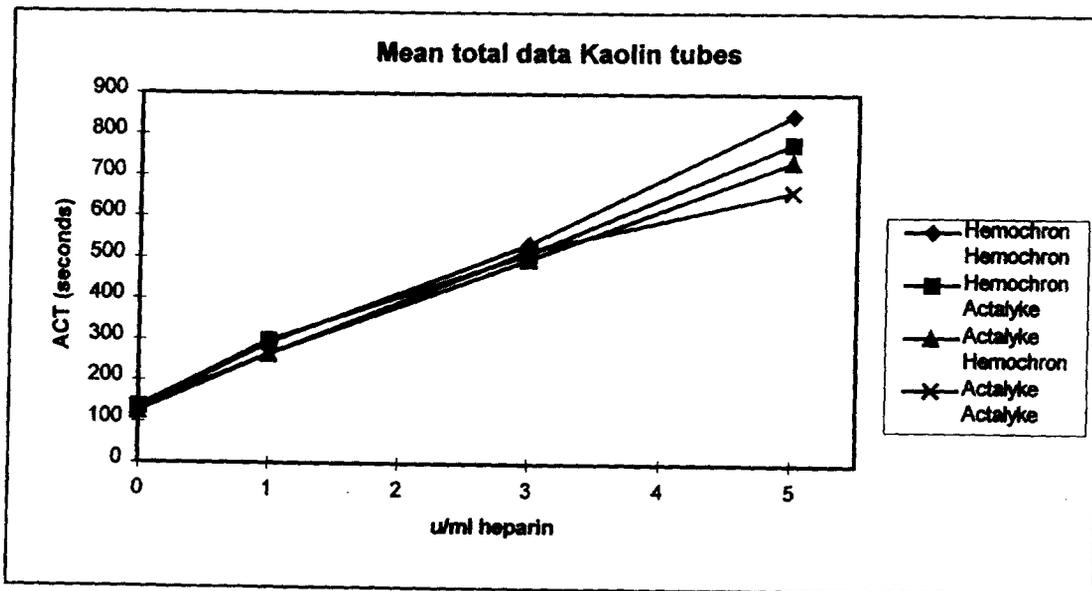


Summary Kaolin tubes

Mean data

u/ml heparin

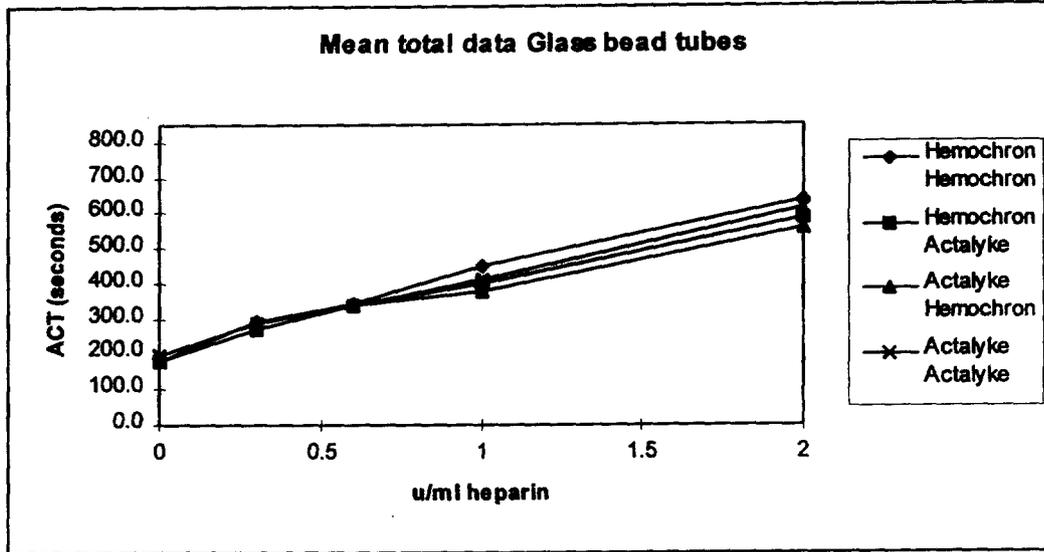
Instrument	tube	0	1	3	5
Hemochron	Hemochron	129.6	291	533.4	848.75
Hemochron	Actalyke	137	297.6	511	780.2
Actalyke	Hemochron	124	264.4	497	735.6



Summary Glass Bead tubes

Mean data u/ml heparin

Instrument	tube	0	0.3	0.6	1	2
Hemochron	Hemochron	179.0	294.4	345.6	451.0	636.2
Hemochron	Actalyke	181.0	270.2	336.0	402.0	584.4
Actalyke	Hemochron	178.4	272.6	337.6	378.4	554.6



DATA SUMMARY

- Actalyke Instrument/Actalyke ACT tubes yielded similar normal ranges when compared to the Hemochron Instrument/Hemochron ACT tubes when utilizing the same normal patient samples
- Actalyke Instrument/Actalyke ACT tubes yielded high correlation with Hemochron Instrument/Hemochron ACT tubes when utilizing the same patient samples
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