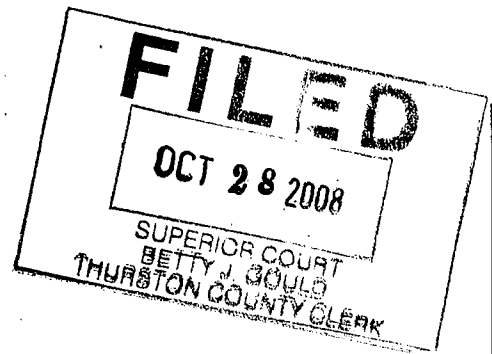


1 ☐ EXPEDITE
2 ☒ No Hearing Set
3 ☐ Hearing is Set
4 Date:
5 Time:
6 (Exparte)



7 **STATE OF WASHINGTON**
8 **THURSTON COUNTY SUPERIOR COURT**

9 In Re the Matter of:

10 **CERAGEM INTERNATIONAL,**
11 **INC., a California corporation,**

12 **Respondent.**

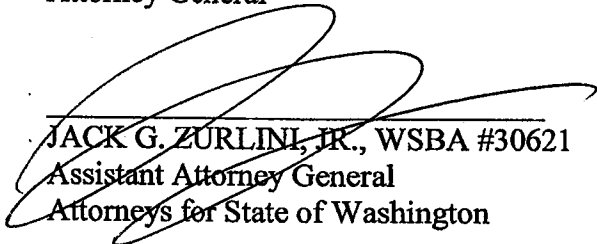
NO. **08-2-02494-3**

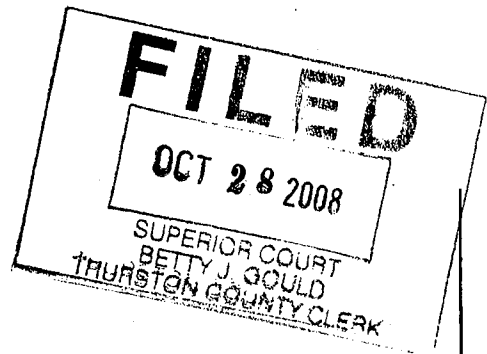
**PETITION FOR ORDER
APPROVING ENTRY OF
ASSURANCE OF
DISCONTINUANCE**

13 **COMES NOW** the State of Washington, by and through its attorneys, Rob McKenna,
14 Attorney General, and Jack G. Zurlini, Jr., Assistant Attorney General, and petitions this Court
15 for an Order Approving Entry of Assurance of Discontinuance.

16 DATED this 27th day of October, 2008.

17 **ROBERT M. McKENNA**
18 **Attorney General**

19 
20 **JACK G. ZURLINI, JR., WSBA #30621**
21 **Assistant Attorney General**
22 **Attorneys for State of Washington**



1 ☐ EXPEDITE
2 ☒ No Hearing Set
3 ☐ Hearing is Set
4 Date:
5 Time:
6 (Exparte)

7 STATE OF WASHINGTON
8 THURSTON COUNTY SUPERIOR COURT

9 In Re the Matter of:

10 CERAGEM INTERNATIONAL,
11 INC., a California corporation,

12 Respondent.

NO. 08-2-02494-3
ORDER APPROVING ENTRY OF
ASSURANCE OF DISCONTINUANCE

13 THE COURT hereby approves and orders entry of the attached Assurance of
14 Discontinuance pursuant to RCW 19.86.100.

15 DATED this 28th day of October, 2008.

16 DAVID HUNTER OF MONTLAW
17 COURT COMMISSIONER

18 COURT COMMISSIONER

19 Presented by:

20 ROBERT M. McKENNA
21 Attorney General

22 By:

23 JACK G. ZURLINI, JR., WSBA #30621
24 Assistant Attorney General
25 Attorneys for State of Washington
26

1 Agreed to, Approved for Entry, and
2 Notice of Presentation Waived by:

3 By:



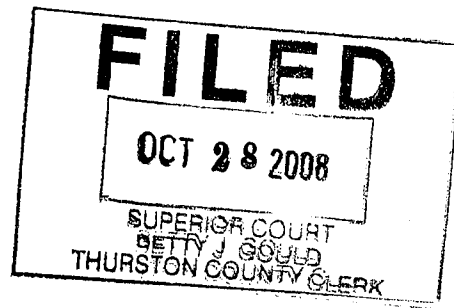
4 THOMAS L. BOEDER, WSBA No. 408

5 KATE VAUGHAN, WSBA No. 35970

6 PERKINS COIE LLP

Attorneys for Ceragem International, Inc.

Dated: 10/21/08



☐ EXPEDITE
☒ No Hearing Set
☐ Hearing is Set
Date:
Time:
(Exparte)

STATE OF WASHINGTON
THURSTON COUNTY SUPERIOR COURT

In Re the Matter of:

CERAGEM INTERNATIONAL,
INC., a California corporation,

Respondent.

NO. **08-2-02494-3**
ASSURANCE OF DISCONTINUANCE

1. GENERAL

1.1. This Assurance of Discontinuance ("Assurance") is between the Attorney General of the State of Washington, and Ceragem International, a California corporation, (Ceragem) and shall be effective as of the date it is filed with the Thurston County Superior Court.

1.2. This Assurance shall be binding on, and apply to, Ceragem and its owners, directors, successors, assigns, transferees, officers, agents, partners, servants, employees, representatives, independent retail distributors of Ceragem products and services, to the extent they have actual or constructive notice, and all other persons acting in concert or participating with Ceragem in the context of conducting Ceragem's business.

1.3. Pursuant to the Washington Consumer Protection Act, RCW Ch. 19.86, the Attorney General has investigated Ceragem's business practices concerning its marketing and sale of massage beds through the Internet and distributors located in Spokane and Kent, Washington.

1 1.4. At this time, the Attorney General has determined to conclude his inquiry and
2 Ceragem has agreed to a set of practices regarding certain aspects of its business as provided by
3 this Assurance.

4 1.5. The Parties agree this Assurance does not constitute evidence or an admission by
5 any party regarding the existence or non-existence of any issue, fact, or violation of any law.

6 1.6. Ceragem recognizes and states that this Assurance is entered into voluntarily and
7 that no promises, representations or threats have been made by the Attorney General's Office or
8 any member, officer, agent or representative thereof to induce them to enter into this Assurance,
9 except for the promises and representations provided herein.

10 1.7. Ceragem further agrees its payments made or due pursuant to this Assurance are
11 not amenable to discharge in bankruptcy and it shall not seek or support their discharge in
12 bankruptcy, nor oppose their being determined not amenable to discharge in bankruptcy.

13 1.8. Ceragem further agrees its payments made or due pursuant to this Assurance are
14 not preferential transfers of assets and it shall not make nor support arguments to the contrary in
15 bankruptcy court or elsewhere.

16 **2. ATTORNEY GENERAL'S ALLEGATIONS**

17 2.1. The Attorney General commenced an investigation into Ceragem's marketing and
18 sales practices of its massage beds in or about November 2006.

19 2.2. The Attorney General alleged, among other things, that:

20 2.2.1. The Ceragem-C Thermal Massager (CCTM) and the Ceragem-RH1
21 Automatic Thermal Massager (CRTM) have been cleared for marketing as over-the-
22 counter, nonprescription, class II medical devices identified by the United States Food and
23 Drug Administration (USFDA).

24 2.2.2. The USFDA issued a Substantial Equivalence letter dated July 28, 2004,
25 identified as 510(k) Number K040031, setting forth the following indications for use of
26 the CCTM for which it is authorized for sale in the United States:

1 "The intended use of the CERAGEM-C Thermal Massager is to provide muscle
2 relaxation therapy by delivering heat and soothing massage. Additionally, the
3 CERAGEM-C Thermal Massager provides radiant infrared heat for:

- 4 --temporary relief of minor muscle and joint pain, and stiffness
- 5 --temporary relief of minor joint pain associated with arthritis
- 6 --temporary increase in local circulation where applied
- 7 --relaxation of muscles"

8 2.2.3. The USFDA issued a Substantial Equivalence letter dated October 31,
9 2006, identified as 510(k) Number K062476, setting forth the following indications for
10 use of the CRTM for which it is authorized for sale in the United States:

11 "The intended use of the CERAGEM-RH1 Automatic Thermal Massager is to provide
12 muscle relaxation therapy by delivering heat and soothing massage. Additionally, the
13 product provides topical radiant infrared heat for:

- 14 --temporary relief of minor muscle and joint pain and stiffness
- 15 --temporary relief of minor joint pain associated with arthritis
- 16 --temporary increase in local circulation where applied
- 17 --relaxation of muscles"

18 2.2.4. In its marketing of the massage beds, Ceragem was to remain within the
19 scope of the indications of usage stated in the USFDA letters and not represent that the
20 beds could provide medical benefits other than those listed in the letters.

21 2.2.5. Among other methods to market its massage beds, Ceragem uses
22 testimonials from individuals who believe they derive some benefits from using the beds.
23 Ceragem trained its distributors to elicit these testimonials and present them to consumers
24 who were at the distributorships. Ceragem's instructions to its distributors did not include
25 first screening the individuals to determine whether the benefits they believed they derived
26 from the massage beds were within the scope of the USFDA letters.

1 2.2.6. Representatives of the Attorney General's Office, Consumer Protection
2 Division, visited the distributor locations in Washington on numerous occasions. The
3 representatives witnessed individuals testifying at the distributorships that they had
4 derived a variety of benefits from using Ceragem's massage beds including that the beds
5 treat, cure, remedy, or correct diseases and medical conditions outside the scope of the
6 USFDA letters.

7 **3. DENIALS BY CERAGEM**

8 3.1. Ceragem denies any allegations that its conduct has been unlawful in any
9 respect and enters into this Assurance solely to avoid the burden and expense of further
10 investigation or litigation.

11 3.2. Ceragem asserts that substantial efforts have been made by Ceragem International
12 to instruct independent distributors regarding marketing of Ceragem products, including regular
13 written reminders to those distributors that they "cannot market, advertise, promote represent or
14 claim that CERAGEM products cure, treat or mitigate any disease or physical conditions other
15 than those approved, pre-cleared or exempted by the USFDA."

16 3.3. Ceragem International has never received a complaint or request for refund from a
17 Washington State consumer.

18 **4. ASSURANCES**

19 4.1. The provisions of this Section 4 shall apply to Ceragem and to its owners,
20 directors, successors, assigns, transferees, officers, agents, partners, servants, employees,
21 representatives, independent retail distributors of Ceragem products and services, to the extent
22 they have actual or constructive notice, and all other persons or entities that act in concert or
23 participate with Ceragem.

24 4.2. Ceragem shall immediately provide to managers having responsibility for
25 operations within the State of Washington, managers having responsibility for Internet
26

1 advertising, and to Ceragem distributors who market Ceragem products to Washington consumers
2 a copy of this Assurance.

3 4.3. For the purposes of resolving all issues between the parties with respect to the
4 marketing of Ceragem products, Ceragem hereby agrees and voluntarily assures the State of
5 Washington that:

6 4.3.1. Ceragem shall not market, advertise, promote, represent, or claim,
7 directly or by implication, that the CCTM or CRTM can provide anything more than
8 radiant infrared heat and massage therapy for the temporary relief of minor muscle and
9 joint pain and stiffness; temporary relief of minor joint pain associated with arthritis;
10 temporary increase in local circulation where applied, and relaxation of muscles, unless
11 otherwise approved, cleared, precleared, or exempted by the USFDA;

12 4.3.2. Ceragem shall train its distributors to avoid by all reasonable means
13 eliciting individual testimonials at distributor locations (or in any other advertisement or
14 promotion) that directly or by implication unlawfully represent or claim that any of
15 Ceragem's products can cure, treat, or mitigate any disease or physical or mental
16 condition other than those approved, cleared, precleared, or exempted by the USFDA;

17 4.3.3. Ceragem shall require its employees and distributors in Washington to
18 prominently display signs in English and any other language that a substantial number
19 of distributor location visitors speak at the entrance and in both the presentation areas
20 and the demonstration areas indicating: (1) the cleared usage of the CCTM and
21 CRTM as per the USFDA letters, as may be subsequently amended, (2) the cleared
22 name of the CCTM and CRTM as per the USFDA letters, and (3) that the CCTM and
23 CRTM are not intended to cure, treat, mitigate, or diagnose any physical or mental
24 disease or condition other than those diseases or conditions indicated in the USFDA
25 letters, as may be subsequently amended; and
26

1 4.3.4. Ceragem shall respond in good faith to buyers' requests for refunds,
2 requests to cancel, complaints, or inquiries, and to offer to resolve the matter in good
3 faith where appropriate.

4 4.4. This Assurance of Discontinuance shall not be considered an admission of
5 violation for any purpose but failure to comply with this Assurance of Discontinuance shall be
6 *prima facie* evidence of violation of RCW 19.86.020 in any enforcement action by the Attorney
7 General seeking remedies such as injunction, restitution, civil penalties, and the costs of suit,
8 including reasonable attorneys' fees.

9 **5. ATTORNEY'S FEES AND COSTS**

10 5.1. Pursuant to RCW 19.86.080, Washington shall recover and Ceragem shall pay the
11 costs and reasonable attorneys' fees incurred by Washington in pursuing this matter in the amount
12 of \$16,000 pursuant to Section 6 of this Assurance.

13 5.2. If not paid when due, interest will accrue on any unpaid balance of attorneys' fees
14 and costs at the rate of twelve percent (12%) per annum.

15 5.3. In any successful action to enforce this Assurance against Ceragem, Ceragem shall
16 bear Washington's reasonable costs of suit, including reasonable attorneys' fees.

17 **6. TERMS OF PAYMENT**

18 6.1. Ceragem shall pay a total of \$16,000, payable on the date this Assurance is entered
19 by the court, or at such other times as agreed to by Washington in writing.

20 6.2. Ceragem shall make all payments to Washington by one or more check payable to
21 the Attorney General - State of Washington, and shall be mailed or delivered to the Office of the
22 Attorney General, Consumer Protection Division, 800 5th Avenue, Suite 2000, Seattle,
23 Washington, 98164-1012 Attention: Cynthia Lockridge, unless otherwise agreed to in writing by
24 Washington.

25 6.3. Ceragem's failure to timely make a payment, without written agreement by
26 Washington, shall be a material breach of this Assurance.

1 **7. ENFORCEMENT**

2 7.1. Under no circumstances shall this Assurance, or the name of the State of
3 Washington, the Office of the Attorney General, the Consumer Protection Division or any of their
4 employees or representatives be used by Ceragem or any of its owners, directors, successors,
5 assigns, transferees, officers, agents, servants, employees, representatives, distributors, and all
6 other persons acting in concert or participating with Ceragem, in connection with any selling,
7 advertising, or promotion of products or services, or as an endorsement or approval of Ceragem's
8 acts, practices, or conduct of business.

9 7.2. Washington shall be permitted, upon thirty (30) days' advance notice to
10 Ceragem, to access, inspect and/or copy, pursuant to RCW 19.86.110, all relevant and non-
11 privileged business records or documents in possession, custody or under control of Ceragem
12 to monitor compliance with this Assurance, provided that the inspection and copying shall be
13 done in such a way as to avoid unreasonable disruption of Ceragem's business activities.

14 7.3. Washington shall be permitted to question Ceragem or any officer, director,
15 agent or employee of Ceragem by deposition, pursuant to the provisions of RCW 19.86.110, to
16 monitor compliance with this Assurance.

17 7.4. Ceragem shall provide Washington with notice of all complaints it receives
18 from Washington residents for a period of one year from the date this Assurance is entered by
19 the court and copies of all documents that memorialize Ceragem's response to each of the
20 complaints. Failure to do so is a material breach of this Assurance.

21 7.5. Nothing in this Assurance shall be construed to limit or bar any other
22 governmental entity or person from pursuing other available remedies against Ceragem or any
23 other person.

24 7.6. Jurisdiction is retained by this court for the purpose of enabling any Party to this
25 Assurance to apply to the court for enforcement of or compliance with this Assurance, to
26 punish violations thereof or clarify the terms of this Assurance.

1 7.7. The invalidity or unenforceability of any particular provision of this Assurance
2 shall not affect the validity of the other provisions of this agreement.

3 7.8. This Assurance may be executed in counterparts and a facsimile signature shall
4 be considered as an original signature.

5 Approved on this 28th day of October, 2008.

6
7 DAVID HUNTER OF MONTLAW
COURT COMMISSIONER

8 COURT COMMISSIONER

9 Presented by:

10 ROBERT M. McKENNA
11 Attorney General

12 By:

13 JACK G. ZURLINI, JR., WSBA No. 30621
Attorneys for State of Washington

14 Agreed to, Approved for Entry, and
15 Notice of Presentation Waived by:

16 CERAGEM INTERNATIONAL, INC.

17 By:

18 Thomas L. Boeder
THOMAS L. BOEDER, WSBA No. 408
19 KATE VAUGHAN, WSBA No. 35970
PERKINS COIE LLP
20 Attorneys for Ceragem International, Inc.

21 Dated: 10/21/08

22 Approved:

23 CERAGEM INTERNATIONAL, INC.

24
25 By: [Signature]

Its

CEO

26 Dated: 10/21/08

ASSURANCE OF DISCONTINUANCE

8

ATTORNEY GENERAL OF WASHINGTON
West 1116 Riverside Avenue
Spokane, WA 99201-1194
(509) 456-3123